正本

檔　　號：
保存年限：

# 衛生福利部食品藥物管理署　函

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受文者：台灣醫療暨生技器材工業同業公會

台灣醫療暨生技器材工業同業公會
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檔號： 109589

發文日期：中華民國109年9月2日
發文字號：FDA器字第1091607785號
速別：普通件
密等及解密條件或保密期限：
附件：

主旨：本署公告「109年度醫療器材標準採認清單」及「廢止或改版之原採認醫療器材標準清單」，請查照。

說明：

一、為促進醫療器材法規國際調和，並協助業者於醫療器材產品研發製造時能有所依循及參考，本署持續推動醫療器材標準採認工作，自93年至108年已陸續公告採認1,051項國內外醫療器材標準。

二、本次公告109年度醫療器材標準採認清單，總計採認1,000項醫療器材標準，包含109年度新增之176項醫療器材採認標準，及原有採認標準但未有改版或廢止情形之醫療器材標準824項。

三、對於歷次公告採認之醫療器材標準，就原標準版本已廢除或改版者，另整理於「廢止或改版之原採認醫療器材標準清單」，請儘早採用相關替代標準。

四、本公告資料載於本署(網址：http://www.fda.gov.tw/)之公告區及醫療器材法規專區。

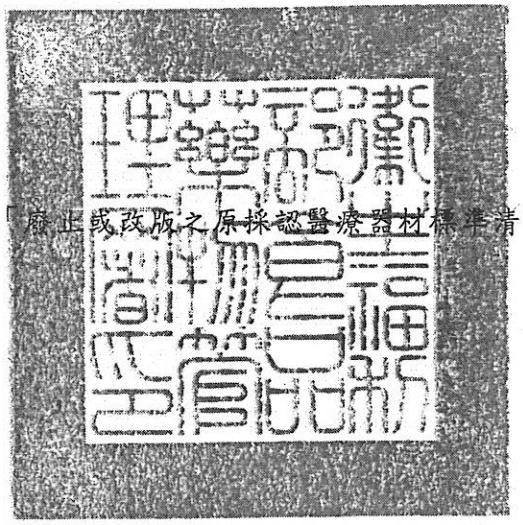
正本：台灣醫療暨生技器材工業同業公會(不含附件)
副本：

署長 吳秀梅

檔　　號：
保存年限：

正本

# 衛生福利部食品藥物管理署　公告



發文日期：中華民國109年9月2日
發文字號：FDA器字第1091607783號
附件：「109年度醫療器材標準採認清單」及「廢止或改版之原採認醫療器材標準清單」各1份

主旨：公告「109年度醫療器材標準採認清單」及「廢止或改版之原採認醫療器材標準清單」，協助業者於研發醫療器材產品時能有所依循及參考。

依據：行政程序法第165條。

公告事項：

一、為促進醫療器材法規國際調和，並協助業者於醫療器材產品研發製造時能有所依循及參考，本署持續推動醫療器材標準採認工作，自93年至108年已陸續公告採認1,051項國內外醫療器材標準，以作為我國醫療器材採認標準。

二、109年度總計採認1,000項醫療器材標準(附件1)，包含109年度新增之176項醫療器材採認標準，及原有採認標準但未有改版或廢止情形之醫療器材標準824項。

三、對於歷次公告採認之醫療器材標準，就原標準版本已廢除或改版者，另整理於「廢止或改版之原採認醫療器材標準清單」(附件2)，請儘早採用相關替代標準。

四、本案另載於本署(網址：http://www.fda.gov.tw/)之公告區及醫療器材法規專區。

署長 吳秀梅

衛生福利部食品藥物管理署醫療器材標準採認資料

**附件 1、109 年度醫療器材採認標準總清單(1,000 項)。**

| 序號 | 標準類別 | TFDA 採認編號 | 標準組織名稱 | 標準號碼 | 版本年份 | 標準名稱 | 採認說明 |
|---|---|---|---|---|---|---|---|
| 1 | 1 Anesthesias 麻醉學 | TFDA-00408 | ISO | ISO 10651-3:1997 | 1997 | Lung ventilators for medical use -- Part 3: Particular requirements for emergency and transport ventilators | 原採認標準 |
| 2 | 1 Anesthesias 麻醉學 | TFDA-00409 | ISO | ISO 10651-4:2002 | 2002 | Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators | 原採認標準 |
| 3 | 1 Anesthesias 麻醉學 | TFDA-00410 | ISO | ISO 10651-5:2006 | 2006 | Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas powered emergency resuscitators | 原採認標準 |
| 4 | 1 Anesthesias 麻醉學 | TFDA-00569 | CNS | CNS 14961 | 2005 | 小型醫療氣體鋼瓶－銷針標示軛式閥接頭 | 原採認標準 |
| 5 | 1 Anesthesias 麻醉學 | TFDA-00570 | CNS | CNS 14962 | 2005 | 氣體鋼瓶－工業與醫療氣體鋼瓶之閥保護帽與閥保護套－設計、結構與試驗 | 原採認標準 |
| 6 | 1 Anesthesias 麻醉學 | TFDA-00571 | CNS | CNS 14963 | 2005 | 醫療用氣體混合器－獨立式氣體混合器 | 原採認標準 |
| 7 | 1 Anesthesias 麻醉學 | TFDA-00574 | CNS | CNS 15004 | 2006 | 醫療氣體管線系統使用之氧氣濃縮機 | 原採認標準 |
| 8 | 1 Anesthesias 麻醉學 | TFDA-00577 | CNS | CNS 15006 | 2006 | 連接於醫療氣體管線系統終端單元之流量計裝置 | 原採認標準 |
| 9 | 1 Anesthesias 麻醉學 | TFDA-00727 | ISO | ISO 5362:2006 | 2006 | Anaesthetic reservoir bags | 原採認標準 |

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| 10 | 1 Anesthesias<br>麻醉學 | TFDA-01156 | CNS | CNS 14776 | 2003 | 醫用面罩對合成血液穿透阻力的試驗法—以已知速度定量的水平噴灑 (Method of test for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)) | 原採認標準 |
| 11 | 1 Anesthesias<br>麻醉學 | TFDA-01157 | CNS | CNS 14777 | 2003 | 醫用面罩空氣交換壓力之試驗法 (Method of test for air exchange pressure of medical face mask) | 原採認標準 |
| 12 | 1 Anesthesias<br>麻醉學 | TFDA-01158 | CNS | CNS 6636 | 2013 | 呼吸防護裝置-氣體濾材及組合型濾材-要求、試驗、標示 (Respiratory protective devices - Gas filters and combined filters - Requirements, testing, marking) | 原採認標準 |
| 13 | 1 Anesthesias<br>麻醉學 | TFDA-01167 | ISO | ISO 23328-1:2003 | 2003 | Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance | 原採認標準 |
| 14 | 1 Anesthesias<br>麻醉學 | TFDA-01168 | ISO | ISO 23328-2:2002 | 2002 | Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects | 原採認標準 |
| 15 | 1 Anesthesias<br>麻醉學 | TFDA-01170 | ISO | ISO 26782:2009/Cor1:2009 | 2009 | Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans | 原採認標準 |
| 16 | 1 Anesthesias<br>麻醉學 | TFDA-01452 | ASTM | ASTM G175-13 | 2013 | Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications | 原採認標準 |
| 17 | 1 Anesthesias<br>麻醉學 | TFDA-01454 | ISO | ISO 10079-2:2014 | 2014 | Medical suction equipment - Part 2: Manually powered suction equipment | 原採認標準 |
| 18 | 1 Anesthesias<br>麻醉學 | TFDA-01455 | ISO | ISO 10079-3:2014 | 2014 | Medical suction equipment Part 3: Suction equipment powered from a vacuum or pressure source | 原採認標準 |

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| 19 | 1 Anesthesias 麻醉學 | TFDA-01456 | ISO | ISO 14408:2016 | 2016 | Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information | 原採認標準 |
| 20 | 1 Anesthesias 麻醉學 | TFDA-01457 | ISO | ISO 23747:2015 | 2015 | Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans | 原採認標準 |
| 21 | 1 Anesthesias 麻醉學 | TFDA-01459 | ISO | ISO 5360:2016 | 2016 | Anaesthetic vaporizers - Agent-specific filling systems | 原採認標準 |
| 22 | 1 Anesthesias 麻醉學 | TFDA-01460 | ISO | ISO 5361:2016 | 2016 | Anaesthetic and respiratory equipment — Tracheal tubes and connectors | 原採認標準 |
| 23 | 1 Anesthesias 麻醉學 | TFDA-01461 | ISO | ISO 5364:2016 | 2016 | Anaesthetic and respiratory equipment - Oropharyngeal airways | 原採認標準 |
| 24 | 1 Anesthesias 麻醉學 | TFDA-01462 | ISO | ISO 5366:2016 | 2016 | Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors | 原採認標準 |
| 25 | 1 Anesthesias 麻醉學 | TFDA-01463 | ISO | ISO 5367:2014 | 2014 | Breathing Tubes intended for use with Anaesthetic Apparatus and Ventilators | 原採認標準 |
| 26 | 1 Anesthesias 麻醉學 | TFDA-01464 | ISO | ISO 7376:2009 | 2009 | Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation | 原採認標準 |
| 27 | 1 Anesthesias 麻醉學 | TFDA-01465 | ISO | ISO 80369-7:2016 | 2016 | Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications | 原採認標準 |
| 28 | 1 Anesthesias 麻醉學 | TFDA-01467 | ISO | ISO 80601-2-67:2014 | 2014 | Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen conserving equipment | 原採認標準 |
| 29 | 1 Anesthesias 麻醉學 | TFDA-01468 | ISO | ISO 80601-2-69:2014 | 2014 | Medical electrical equipment Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment | 原採認標準 |
| 30 | 1 Anesthesias 麻醉學 | TFDA-01765 | ISO | ISO 10524-1: 2018 | 2018 | Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow-metering devices | 原採認標準 |

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| 31 | 1 Anesthesias 麻醉學 | TFDA-01766 | ISO | ISO 10524-2: 2018 | 2018 | Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators | 原採認標準 |
| 32 | 1 Anesthesias 麻醉學 | TFDA-01767 | ISO | ISO 17510:2015 | 2015 | Medical devices - Sleep apnoea breathing therapy - Masks and application accessories | 原採認標準 |
| 33 | 1 Anesthesias 麻醉學 | TFDA-01768 | ISO | ISO 5356-1:2015 | 2015 | Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets | 原採認標準 |
| 34 | 1 Anesthesias 麻醉學 | TFDA-01770 | ISO | ISO 5359:2014/AMD 1:2017 | 2017 | Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases | 原採認標準 |
| 35 | 1 Anesthesias 麻醉學 | TFDA-01771 | ISO | ISO 80601-2-55:2018 | 2018 | Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors | 原採認標準 |
| 36 | 1 Anesthesias 麻醉學 | TFDA-01772 | ISO | ISO 80601-2-70:2015 | 2015 | Medical Electrical Equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment | 原採認標準 |
| 37 | 1 Anesthesias 麻醉學 | TFDA-01773 | ISO | ISO 80601-2-74:2017 | 2017 | Medical electrical equipment—Part 2–74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment | 原採認標準 |
| 38 | 1 Anesthesias 麻醉學 | TFDA-01873 | ISO | ISO 10079-1:2015 /AMD 1:2018 | 2018 | Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements | 原採認標準 |
| 39 | 1 Anesthesias 麻醉學 | TFDA-01874 | IEC | ISO 80601-2-13: 2011/Amd 2:2018 | 2011 | Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation | 原採認標準 |
| 40 | 1 Anesthesias 麻醉學 | TFDA-01930 | EN | EN ISO 27427 : 2019 | 2019 | Anaesthetic and respiratory equipment - Nebulizing systems and components | 109 年度新增採認標準 |
| 41 | 1 Anesthesias 麻醉學 | TFDA-01931 | ISO | ISO 10524-3:2019 | 2019 | Pressure regulators for use with medical gases – Part 3:Pressure regulators integrated with cylinder valves | 109 年度新增採認標準 |

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| 42 | 1 Anesthesias 麻醉學 | TFDA-01932 | ISO | ISO 80369-1:2018 | 2018 | Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements | 109 年度新增採認標準 |
| 43 | 1 Anesthesias 麻醉學 | TFDA-01933 | ISO | ISO 10079-1/AMD 1:2018 | 2018 | Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements | 109 年度新增採認標準 |
| 44 | 1 Anesthesias 麻醉學 | TFDA-01934 | ISO | ISO 80601-2-12:2020 | 2020 | Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators | 109 年度新增採認標準 |
| 45 | 1 Anesthesias 麻醉學 | TFDA-01935 | ISO | ISO 8836:2019 | 2019 | Suction catheters for use in the respiratory tract | 109 年度新增採認標準 |
| 46 | 1 Anesthesias 麻醉學 | TFDA-01936 | ISO | ISO 5356-2:2012 /AMD 1:2019 | 2019 | Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors | 109 年度新增採認標準 |
| 47 | 2 Biocompatibility 生物相容性 | TFDA-00021 | ISO | ISO 10993-14:2001 | 2001 | Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics | 原採認標準 |
| 48 | 2 Biocompatibility 生物相容性 | TFDA-00024 | ISO | ISO 10993-17:2002 | 2002 | Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances | 原採認標準 |
| 49 | 2 Biocompatibility 生物相容性 | TFDA-00234 | CNS | CNS 14393-7 | 2005 | 醫療器材生物性評估－第７部：環氧乙烷滅菌之殘留物 Biological evaluation of medical devices - Part 7: ethylene oxide sterilisation residuals | 原採認標準 |
| 50 | 2 Biocompatibility 生物相容性 | TFDA-00235 | CNS | CNS 14393-8 | 2005 | 醫療器材生物性評估－第８部：生物測試用參考材料之選擇及資格認定 Biological evaluation of medical devices - Part 8: Selection and qualification of reference materials for biological tests (ISO 10993-8:2000) | 原採認標準 |
| 51 | 2 Biocompatibility 生物相容性 | TFDA-00236 | CNS | CNS 14393-10 | 2005 | 醫療器材生物性評估－第１０部：刺激性及延遲型過敏性測試 Biological evaluation of medical devices - Part 10 : tests for irritation and sensitisation | 原採認標準 |

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| 52 | 2 Biocompatibility 生物相容性 | TFDA-00237 | CNS | CNS 14393-12 | 2005 | 醫療器材生物性評估－第１２部：樣品製備及參考材料 Biological evaluation of medical devices - Part 12 : sample preparation and reference materials | 原採認標準 |
| 53 | 2 Biocompatibility 生物相容性 | TFDA-00238 | CNS | CNS 14393-6 | 2004 | 醫療器材生物性評估－第六部分:植入後的局部效應測試 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation | 原採認標準 |
| 54 | 2 Biocompatibility 生物相容性 | TFDA-00239 | CNS | CNS 14393-11 | 2005 | 醫療器材生物性評估－第１１部：全身毒性測試 Biological evaluation of medical devices - Part 11: tests for systemic toxicity | 原採認標準 |
| 55 | 2 Biocompatibility 生物相容性 | TFDA-00348 | ISO | ISO/TS 10993-20:2006 | 2006 | Biological evaluation of medical devices —Part 20: Principles and methods for immunotoxicology testing of medical devices | 原採認標準 |
| 56 | 2 Biocompatibility 生物相容性 | TFDA-00361 | ISO | ISO 10993-2:2006 | 2006 | Biological evaluation of medical devices -- Part 2: Animal welfare requirements | 原採認標準 |
| 57 | 2 Biocompatibility 生物相容性 | TFDA-00363 | CNS | CNS14393-1 | 2004 | 醫療器材生物性評估-第一部份：評估與試驗 | 原採認標準 |
| 58 | 2 Biocompatibility 生物相容性 | TFDA-00364 | CNS | CNS14393-2 | 2004 | 醫療器材生物性評估-第二部份：動物福利之規定 | 原採認標準 |
| 59 | 2 Biocompatibility 生物相容性 | TFDA-00365 | CNS | CNS14393-3 | 2004 | 醫療器材生物性評估-第三部份：基因毒性、致癌性與生殖毒性之試驗 | 原採認標準 |
| 60 | 2 Biocompatibility 生物相容性 | TFDA-00366 | CNS | CNS14393-4 | 2004 | 醫療器材生物性評估-第四部份：血液接觸特性測試方法的選擇 | 原採認標準 |
| 61 | 2 Biocompatibility 生物相容性 | TFDA-00367 | CNS | CNS14393-5 | 2004 | 醫療器材生物性評估-第五部份：體外細胞毒性試驗 | 原採認標準 |
| 62 | 2 Biocompatibility 生物相容性 | TFDA-00368 | CNS | CNS14393-9 | 2005 | 醫療器材生物性評估-第九部份：潛在降解產物之鑑別與定量分析架構 | 原採認標準 |

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| 63 | 2 Biocompatibility 生物相容性 | TFDA-00369 | CNS | CNS14393-13 | 2005 | 醫療器材生物性評估-第十三部份：聚合物醫療器材降解產物之鑑別與定量 | 原採認標準 |
| 64 | 2 Biocompatibility 生物相容性 | TFDA-00370 | CNS | CNS14393-14 | 2005 | 醫療器材生物性評估-第十四部份：陶瓷降解產物之鑑別與定量 | 原採認標準 |
| 65 | 2 Biocompatibility 生物相容性 | TFDA-00371 | CNS | CNS14393-15 | 2006 | 醫療器材生物性評估-第十五部份：金屬集合金之降解產物的鑑別與定量 | 原採認標準 |
| 66 | 2 Biocompatibility 生物相容性 | TFDA-00372 | CNS | CNS14393-16 | 2006 | 醫療器材生物性評估-第十六部份：降解及可溶出物之毒性動力學之研究設計 | 原採認標準 |
| 67 | 2 Biocompatibility 生物相容性 | TFDA-00743 | CNS | CNS 15153 | 2007 | 醫療器材生物性評估－第 17 部：可溶出物質容忍限量之建立 | 原採認標準 |
| 68 | 2 Biocompatibility 生物相容性 | TFDA-00744 | CNS | CNS 15154 | 2007 | 醫療器材生物性評估－第 18 部：材料之化學特性 | 原採認標準 |
| 69 | 2 Biocompatibility 生物相容性 | TFDA-00745 | CNS | CNS 15155 | 2007 | 醫療器材生物性評估－第 19 部：材料之物理化學、形態及拓撲學的特性分析 | 原採認標準 |
| 70 | 2 Biocompatibility 生物相容性 | TFDA-00746 | CNS | CNS 14393-20 | 2009 | 醫療器材生物性評估－第 20 部：醫療器材免疫毒理學試驗之原理與方法 | 原採認標準 |
| 71 | 2 Biocompatibility 生物相容性 | TFDA-00858 | ISO | ISO 10993-5:2009 | 2009 | Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity | 原採認標準 |
| 72 | 2 Biocompatibility 生物相容性 | TFDA-00860 | ISO | ISO 10993-13:2010 | 2010 | Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices | 原採認標準 |
| 73 | 2 Biocompatibility 生物相容性 | TFDA-00862 | ISO | ISO 10993-10:2010 | 2010 | Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization | 原採認標準 |
| 74 | 2 Biocompatibility 生物相容性 | TFDA-01022 | ASTM | ASTM F750-87/(R)2012 | 2012 | Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse | 原採認標準 |

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| 75 | 2 Biocompatibility 生物相容性 | TFDA-01023 | ASTM | F813 - 07(2012) | 2012 | Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices | 原採認標準 |
| 76 | 2 Biocompatibility 生物相容性 | TFDA-01024 | ISO | ISO 10993-12:2012 | 2012 | Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials | 原採認標準 |
| 77 | 2 Biocompatibility 生物相容性 | TFDA-01471 | ISO | ISO 10993-3:2014 | 2014 | Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity | 原採認標準 |
| 78 | 2 Biocompatibility 生物相容性 | TFDA-01472 | ISO | ISO 10993-6:2016 | 2016 | Biological evaluation of medical devices, Part 6: Tests for local effects after implantation | 原採認標準 |
| 79 | 2 Biocompatibility 生物相容性 | TFDA-01473 | ISO | AAMI/ISO TIR37137:2014 | 2014 | Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants | 原採認標準 |
| 80 | 2 Biocompatibility 生物相容性 | TFDA-01474 | ISO | ISO/TR 10993-33 :2015 | 2015 | Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3 - First Edition | 原採認標準 |
| 81 | 2 Biocompatibility 生物相容性 | TFDA-01775 | ASTM | ASTM F720-17 | 2017 | Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test | 原採認標準 |
| 82 | 2 Biocompatibility 生物相容性 | TFDA-01776 | ISO | ISO 10993-11:2017 | 2017 | Biological evaluation of medical devices -- Part 11:Tests for systemic toxicity | 原採認標準 |
| 83 | 2 Biocompatibility 生物相容性 | TFDA-01777 | ISO | ISO 10993-16:2017 | 2017 | Biological evaluation of medical devices -- Part 16:Toxicokinetic study design for degradation products and leachables | 原採認標準 |
| 84 | 2 Biocompatibility 生物相容性 | TFDA-01778 | ISO | ISO 10993-4:2017 | 2017 | Biological evaluation of medical devices -- Part 4:Selection of tests for interactions with blood | 原採認標準 |
| 85 | 2 Biocompatibility 生物相容性 | TFDA-01779 | ISO | ISO 18562-1:2017 | 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process | 原採認標準 |

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| 86 | 2 Biocompatibility 生物相容性 | TFDA-01780 | ISO | ISO 18562-2:2017 | 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter | 原採認標準 |
| 87 | 2 Biocompatibility 生物相容性 | TFDA-01781 | ISO | ISO 18562-3:2017 | 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs) | 原採認標準 |
| 88 | 2 Biocompatibility 生物相容性 | TFDA-01782 | ISO | ISO 18562-4:2017 | 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate | 原採認標準 |
| 89 | 2 Biocompatibility 生物相容性 | TFDA-01875 | ASTM | ASTM F2382 - 18 | 2018 | Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT) | 原採認標準 |
| 90 | 2 Biocompatibility 生物相容性 | TFDA-01937 | ISO | ISO 10993-1:2018 | 2018 | Biological evaluation of medical devices -- Part 1:Evaluation and testing within a risk management process | 109 年度新增採認標準 |
| 91 | 2 Biocompatibility 生物相容性 | TFDA-01938 | ASTM | ASTM F2148-18 | 2018 | Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA) | 109 年度新增採認標準 |
| 92 | 2 Biocompatibility 生物相容性 | TFDA-01939 | ISO | ISO 10993-15:2019 | 2019 | Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals an | 109 年度新增採認標準 |
| 93 | 2 Biocompatibility 生物相容性 | TFDA-01940 | ISO | ISO 10993-18:2020 | 2020 | Biological evaluation of medical devices —Part 18: Chemical characterization of materials | 109 年度新增採認標準 |
| 94 | 2 Biocompatibility 生物相容性 | TFDA-01941 | ISO | ISO/TS 10993-19:2020 | 2020 | Biological evaluation of medical devices —Part 19: Physico-chemical, morphological and topographical characterization of materials | 109 年度新增採認標準 |
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| 96 | 2 Biocompatibility 生物相容性 | TFDA-01943 | ASTM | ASTM F719 - 20 | 2020 | Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation | 109 年度新增採認標準 |

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| 97 | 2 Biocompatibility 生物相容性 | TFDA-01944 | ASTM | ASTM F749 - 20 | 2020 | Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit | 109 年度新增採認標準 |
| 98 | 2 Biocompatibility 生物相容性 | TFDA-01945 | ISO | ISO 10993-7:2008 /Amd 1:2019 | 2019 | Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals | 109 年度新增採認標準 |
| 99 | 3 Cardiovascular 心臟血管醫學 | TFDA-00314 | ISO | ISO 11318:2002 | 2002 | Cardiac Defibrillators - Connector Assembly for Implantable Defibrillators - Dimensional and Test Requirements | 原採認標準 |
| 100 | 3 Cardiovascular 心臟血管醫學 | TFDA-00780 | CNS | CNS 13075 | 2007 | 非侵入式自動血壓計 | 原採認標準 |
| 101 | 3 Cardiovascular 心臟血管醫學 | TFDA-00781 | CNS | CNS 15041-1 | 2007 | 非侵入式血壓計－第 1 部：一般規定 | 原採認標準 |
| 102 | 3 Cardiovascular 心臟血管醫學 | TFDA-00782 | CNS | CNS 15041-2 | 2007 | 非侵入式血壓計－第 2 部：機械式血壓計之補充規定 | 原採認標準 |
| 103 | 3 Cardiovascular 心臟血管醫學 | TFDA-00783 | CNS | CNS 15041-3 | 2007 | 非侵入式血壓計－第 3 部：機電式血壓量測系統的補充規定 | 原採認標準 |
| 104 | 3 Cardiovascular 心臟血管醫學 | TFDA-00975 | OIML | OIML R16-2:2002 | 2002 | Non-invasive automated sphygmomanometers | 原採認標準 |
| 105 | 3 Cardiovascular 心臟血管醫學 | TFDA-00978 | CEN | EN 1060-4:2004 | 2004 | Non-invasive sphygmomanometers—Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers | 原採認標準 |
| 106 | 3 Cardiovascular 心臟血管醫學 | TFDA-01179 | AAMI | AAMI EC53:2013 | 2013 | ECG cables and leadwires | 原採認標準 |
| 107 | 3 Cardiovascular 心臟血管醫學 | TFDA-01180 | AAMI | AAMI EC57:2012 | 2012 | Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms | 原採認標準 |

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| 108 | 3 Cardiovascular 心臟血管醫學 | TFDA-01181 | AAMI | AAMI/IEC 60601-2-4:2010 | 2010 | Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators | 原採認標準 |
| 109 | 3 Cardiovascular 心臟血管醫學 | TFDA-01195 | CEN | EN 1060-3:1997 +A2:2009 | 2009 | Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems | 原採認標準 |
| 110 | 3 Cardiovascular 心臟血管醫學 | TFDA-01198 | CEN | EN ISO 81060-1:2012 | 2012 | Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type - CORR: July 31, 2012 | 原採認標準 |
| 111 | 3 Cardiovascular 心臟血管醫學 | TFDA-01200 | ISO | ISO 5841-2:2014 | 2014 | Implants for Surgery - Cardiac Pacemakers - Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads - Third Edition | 原採認標準 |
| 112 | 3 Cardiovascular 心臟血管醫學 | TFDA-01203 | IEC | IEC 60601-2-34:2011 ed3.0 | 2011 | Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment | 原採認標準 |
| 113 | 3 Cardiovascular 心臟血管醫學 | TFDA-01205 | IEC | IEC 60601-2-47:2012 ed2.0 | 2012 | Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems | 原採認標準 |
| 114 | 3 Cardiovascular 心臟血管醫學 | TFDA-01208 | ISO | ISO 10555-4:2013 | 2013 | Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters - Second Edition | 原採認標準 |
| 115 | 3 Cardiovascular 心臟血管醫學 | TFDA-01210 | ISO | ISO 17475:2005 | 2005 | Corrosion of metals and alloys -- Electrochemical test methods -- Guidelines for conducting potentiostatic and potentiodynamic polarization measurements | 原採認標準 |
| 116 | 3 Cardiovascular 心臟血管醫學 | TFDA-01211 | ISO | ISO 2248:1985 | 1985 | Packaging -- Complete, filled transport packages -- Vertical impact test by dropping | 原採認標準 |
| 117 | 3 Cardiovascular 心臟血管醫學 | TFDA-01213 | ISO | ISO 25539-2:2012 | 2012 | Cardiovascular implants - Endovascular devices - Part 2: Vascular stents | 原採認標準 |

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| 118 | 3 Cardiovascular 心臟血管醫學 | TFDA-01214 | ISO | ISO 25539-3:2011 | 2011 | Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters | 原採認標準 |
| 119 | 3 Cardiovascular 心臟血管醫學 | TFDA-01215 | ISO | ISO 5841-3:2013 | 2013 | Implants for surgery -- Cardiac pacemakers -- Part 3: Low-profile connectors (IS-1) for implantable pacemakers | 原採認標準 |
| 120 | 3 Cardiovascular 心臟血管醫學 | TFDA-01218 | ISO | ISO 81060-1:2007 | 2007 | Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type. | 原採認標準 |
| 121 | 3 Cardiovascular 心臟血管醫學 | TFDA-01220 | ISO | ISO 8318:2000 | 2000 | Packaging - Complete, Filled Transport Packages and Unit Laods - Sinusoidal Vibration Tests Using a Variable Frequency - Second Edition | 原採認標準 |
| 122 | 3 Cardiovascular 心臟血管醫學 | TFDA-01478 | ASTM | ASTM F2082/F2082M-16 | 2016 | Standard Test Method for Determination of Transformation Temperature of Nickel- Titanium Shape Memory Alloys by Bend and Free Recovery | 原採認標準 |
| 123 | 3 Cardiovascular 心臟血管醫學 | TFDA-01481 | ASTM | ASTM F3036-13 | 2013 | Standard Guide for Testing Absorbable Stents | 原採認標準 |
| 124 | 3 Cardiovascular 心臟血管醫學 | TFDA-01482 | IEC | IEC 60601-2-27:2011 | 2011 | Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment | 原採認標準 |
| 125 | 3 Cardiovascular 心臟血管醫學 | TFDA-01485 | ISO | ISO 15676:2016 | 2016 | Cardiovascular implants and artificial organs - Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) | 原採認標準 |
| 126 | 3 Cardiovascular 心臟血管醫學 | TFDA-01486 | ISO | ISO 25539-1:2017 | 2017 | Cardiovascular implants— Endovascular devices—Part 1: Endovascular prostheses | 原採認標準 |
| 127 | 3 Cardiovascular 心臟血管醫學 | TFDA-01487 | ISO | ISO 5840-1:2015 | 2015 | Cardiovascular implants — Cardiac valve prostheses Part 1: General requirements | 原採認標準 |
| 128 | 3 Cardiovascular 心臟血管醫學 | TFDA-01488 | ISO | ISO 5840-2:2015 | 2015 | Cardiovascular implants — Cardiac valve prostheses Part 2: Surgically implanted heart valve substitutes | 原採認標準 |

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| 129 | 3 Cardiovascular 心臟血管醫學 | TFDA-01489 | ISO | ISO 5840-3:2013 | 2013 | Cardiovascular implants - Cardiac valve prostheses Part 3: Heart valve substitutes implanted by transcatheter techniques | 原採認標準 |
| 130 | 3 Cardiovascular 心臟血管醫學 | TFDA-01490 | ISO | ISO 7198:2016 | 2016 | Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches | 原採認標準 |
| 131 | 3 Cardiovascular 心臟血管醫學 | TFDA-01492 | ISO | ISO 12417-1:2015 | 2015 | Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements | 原採認標準 |
| 132 | 3 Cardiovascular 心臟血管醫學 | TFDA-01783 | ASTM | ASTM F2004-17 | 2017 | Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis | 原採認標準 |
| 133 | 3 Cardiovascular 心臟血管醫學 | TFDA-01784 | IEC | IEC 60601-2-4:2010 +AMD1:2018 | 2018 | Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators | 原採認標準 |
| 134 | 3 Cardiovascular 心臟血管醫學 | TFDA-01785 | IEC | IEC 80601-2-30:2018 | 2018 | Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers | 原採認標準 |
| 135 | 3 Cardiovascular 心臟血管醫學 | TFDA-01786 | IEC | IEC 80601-2-49:2018 | 2018 | Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors | 原採認標準 |
| 136 | 3 Cardiovascular 心臟血管醫學 | TFDA-01787 | ISO | ISO 11070 :2014 +A1:2018 | 2014 | Sterile single-use intravascular introducers, dilators and guidewires | 原採認標準 |
| 137 | 3 Cardiovascular 心臟血管醫學 | TFDA-01788 | ISO | ISO 80601-2-61:2017 | 2017 | Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment | 原採認標準 |
| 138 | 3 Cardiovascular 心臟血管醫學 | TFDA-01876 | AAMI | AMMI EC12:2000/(R2015) | 2015 | Disposable ECG electrodes | 原採認標準 |
| 139 | 3 Cardiovascular 心臟血管醫學 | TFDA-01877 | AAMI | IEC 60601-2-25 :2011(R2016) | 2016 | Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs. | 原採認標準 |

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| 140 | 3 Cardiovascular 心臟血管醫學 | TFDA-01878 | ASTM | ASTM F2081 - 06(2017) | 2017 | Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents | 原採認標準 |
| 141 | 3 Cardiovascular 心臟血管醫學 | TFDA-01879 | ASTM | ASTM F1984 - 99(2018) | 2018 | Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials | 原採認標準 |
| 142 | 3 Cardiovascular 心臟血管醫學 | TFDA-01880 | ASTM | ASTM F2079 - 09(2017) | 2017 | Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon Expandable Stents | 原採認標準 |
| 143 | 3 Cardiovascular 心臟血管醫學 | TFDA-01881 | ASTM | ASTM F2394 - 07(2017) | 2017 | Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System | 原採認標準 |
| 144 | 3 Cardiovascular 心臟血管醫學 | TFDA-01882 | ASTM | ASTM F746 - 04(2014) | 2014 | Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials | 原採認標準 |
| 145 | 3 Cardiovascular 心臟血管醫學 | TFDA-01946 | ISO | ISO 8637-3:2018 | 2018 | Extracorporeal systems for blood purification - Part 3: Plasmafilters | 109 年度新增採認標準 |
| 146 | 3 Cardiovascular 心臟血管醫學 | TFDA-01947 | ISO | ISO 81060-2:2018 /AMD 1:2020 | 2020 | Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type - Second Edition | 109 年度新增採認標準 |
| 147 | 3 Cardiovascular 心臟血管醫學 | TFDA-01948 | ASTM | ASTM F3320-18 | 2018 | Standard Guide for Coating Characterization of Drug Coated Balloons | 109 年度新增採認標準 |
| 148 | 3 Cardiovascular 心臟血管醫學 | TFDA-01949 | ISO | ISO 5910:2018 | 2018 | Cardiovascular implants and extracorporeal systems - Cardiac valve repair devices | 109 年度新增採認標準 |
| 149 | 3 Cardiovascular 心臟血管醫學 | TFDA-01950 | AAMI | AAMI/ISO 14117:2019 | 2019 | Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices. | 109 年度新增採認標準 |
| 150 | 3 Cardiovascular 心臟血管醫學 | TFDA-01951 | ASTM | ASTM G71 - 81(2019) | 2019 | Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes | 109 年度新增採認標準 |

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| 151 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01952 | IEC | IEC<br>60601-2-31:2020 | 2020 | Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source | 109 年度新增採認標準 |
| 152 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01953 | ISO | ISO 14708-2:2019 | 2019 | Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers | 109 年度新增採認標準 |
| 153 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01954 | ASTM | ASTM F138 - 19 | 2019 | Standard Specification for Wrought 18 Chromium 14 Nickel 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673) | 109 年度新增採認標準 |
| 154 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01955 | ASTM | ASTM F2942 - 19 | 2019 | Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents | 109 年度新增採認標準 |
| 155 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01956 | ISO | ISO 15674:2016<br>/AMD 1:2020 | 2020 | Cardiovascular implants and artificial organs - Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags | 109 年度新增採認標準 |
| 156 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01957 | ISO | ISO 15675:2016<br>/AMD 1:2020 | 2020 | Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters | 109 年度新增採認標準 |
| 157 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01958 | ISO | ISO 7199:2016/AMD 1:2020 | 2020 | Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) | 109 年度新增採認標準 |
| 158 | 3 Cardiovascular<br>心臟血管醫學 | TFDA-01959 | ISO | ISO/TS 17137:2019 | 2019 | Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants | 109 年度新增採認標準 |
| 159 | 4 Dental/ENT<br>牙科學/耳鼻喉科學 | TFDA-00373 | ANSI | ADA Specification No.27-1993 | 1993 | Resin-Based Filling Materials | 原採認標準 |
| 160 | 4 Dental/ENT<br>牙科學/耳鼻喉科學 | TFDA-00381 | ISO | ISO 6360-3: 2005 | 2005 | Dentistry -- Number coding system for rotary instruments -- Part 3: Specific characteristics of burs and cutters | 原採認標準 |

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| 161 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00382 | ISO | ISO 6360-4: 2004 | 2004 | Dentistry -- Number coding system for rotary instruments -- Part 4: Specific characteristics of diamond instruments | 原採認標準 |
| 162 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00383 | ISO | ISO 6360-6: 2004 | 2004 | Dentistry -- Number coding system for rotary instruments -- Part 6: Specific characteristics of abrasive instruments | 原採認標準 |
| 163 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00384 | ISO | ISO 6360-7: 2006 | 2006 | Dentistry – Number coding system for rotary instruments – Part 7: Specific characteristics of mandrels and special instruments | 原採認標準 |
| 164 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00385 | ISO | ISO 13397-1:1995 | 1995 | Periodontal curettes, dental scalers and excavators -- Part 1: General requirements | 原採認標準 |
| 165 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00387 | ISO | ISO 13397-3:1996 | 1996 | Periodontal curettes, dental scalers and excavators -- Part 3: Dental scalers -- H-type | 原採認標準 |
| 166 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00388 | ISO | ISO 13397-4:1997 | 1997 | Periodontal curettes, dental scalers and excavators -- Part 4: Dental excavators -- Discoid-type | 原採認標準 |
| 167 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00389 | ISO | ISO 15854:2005 | 2005 | Dentistry – Casting and baseplate waxes | 原採認標準 |
| 168 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00687 | ISO | ISO 6877:2006 | 2006 | Dentistry -- Root-canal obturating points | 原採認標準 |
| 169 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00690 | ISO | ISO 9917-1:2007 | 2007 | Dentistry -- Water-based cements -- Part 1: Powder/liquid acid-base cements | 原採認標準 |
| 170 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00873 | ISO | ISO 9168:2009 | 2009 | Dentistry -- Hose connectors for air driven dental handpieces | 原採認標準 |
| 171 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01223 | CEN | EN 1639:2009 | 2009 | Dentistry. Medical devices for dentistry. Instruments | 原採認標準 |
| 172 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01224 | CEN | EN 1640:2009 | 2009 | Dentistry. Medical devices for dentistry. Equipment | 原採認標準 |

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| 173 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01225 | CEN | EN 1641:2009 | 2009 | Dentistry. Medical devices for dentistry. Materials | 原採認標準 |
| 174 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01226 | CEN | EN 1642:2011 | 2011 | Dentistry. Medical devices for dentistry. Dental implants | 原採認標準 |
| 175 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01229 | ISO | ISO 13397-2:2005/Amd1: 2012 | 2012 | Dentistry – Periodontal curettes, dental scalers and excavators – Part 2:Periodontal curettes of Gr-type | 原採認標準 |
| 176 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01232 | ISO | ISO 21563:2013 | 2013 | Dentistry - Hydrocolloid impression materials - First Edition | 原採認標準 |
| 177 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01233 | ISO | ISO 3107:2011 | 2011 | Dentistry — Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements - Fourth Edition | 原採認標準 |
| 178 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01234 | ISO | ISO 6360-2:2004/Amd 1:2011 | 2011 | Dentistry — Number coding system for rotary instruments — Part 2: Shapes AMENDMENT 1 - Second Edition | 原採認標準 |
| 179 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01235 | ISO | ISO 6876:2012 | 2012 | Dentistry - Root canal sealing materials - Third Edition | 原採認標準 |
| 180 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01238 | ADA | ANSI/ADA 96-2012 | 2012 | ANSI/ADA Standard No. 96—Dental Water-based Cements: 2012 | 原採認標準 |
| 181 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01494 | AAMI | AAMI CI86:2017 | 2017 | Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting | 原採認標準 |
| 182 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01497 | ISO | ISO 10139-2:2016 | 2016 | Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use | 原採認標準 |
| 183 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01498 | ISO | ISO 14801:2016 | 2016 | Dentistry - Implants - Dynamic loading test for endosseous dental implants | 原採認標準 |

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| 184 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01499 | ISO | ISO 22674:2016 | 2016 | Dentistry -- Metallic materials for fixed and removable restorations and appliances | 原採認標準 |
| 185 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01500 | ISO | ISO 6360-1:2004/Cor1:2007 | 2007 | Dentistry — Number coding system for rotary instruments — Part 1: General characteristics | 原採認標準 |
| 186 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01502 | ISO | ISO 6874:2015 | 2015 | Dentistry — Polymer-based pit and fissure sealants | 原採認標準 |
| 187 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01504 | ISO | ISO 7494-2:2015 | 2015 | Dentistry - Dental units - Part 2: Air, water, suction and wastewater systems - Second Edition | 原採認標準 |
| 188 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01789 | ISO | ISO 10139-1:2018 | 2018 | Dentistry - Soft lining materials for removable dentures - Part 1:Materials for short-term use | 原採認標準 |
| 189 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01790 | ISO | ISO 10477:2018 | 2018 | Dentistry -- Polymer-based crown and bridge materials | 原採認標準 |
| 190 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01791 | ISO | ISO 11137-3:2017 | 2017 | Sterilization of health care products —Radiation —Part 3:Guidance on dosimetric aspects | 原採認標準 |
| 191 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01792 | ISO | ISO 14457:2017 | 2017 | Dentistry -- Handpieces and motors | 原採認標準 |
| 192 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01793 | ISO | ISO 22112:2107 | 2017 | Dentistry - Artificial teeth for dental prostheses | 原採認標準 |
| 193 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01794 | ISO | ISO 7491:2000 | 2000 | Dental materials—Determination of colour stability | 原採認標準 |
| 194 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01795 | ISO | ISO 7494-1:2018 | 2018 | Dentistry -- Dental units -- Part 1: General requirements and test methods | 原採認標準 |

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| 195 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01796 | ISO | ISO 9917-2:2017 | 2017 | Dentistry - Water-based cements - Part 2: Resin-modified cements | 原採認標準 |
| 196 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01883 | ASA | ASA S3.6-2018 | 2018 | American National Standard Specification for Audiometers | 原採認標準 |
| 197 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01884 | ISO | ISO 6872:2015/AMD 1:2018 | 2018 | Dentistry - Ceramic materials | 原採認標準 |
| 198 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01960 | ISO | ISO 9693:2019 | 2019 | Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems | 109 年度新增採認標準 |
| 199 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01961 | ASTM | ASTM F1088-18 | 2018 | Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation | 109 年度新增採認標準 |
| 200 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01962 | ISO | ISO 7405:2018 | 2018 | Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry | 109 年度新增採認標準 |
| 201 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01963 | ISO | ISO 17730:2014 | 2014 | Dentistry - Fluoride varnishes | 109 年度新增採認標準 |
| 202 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01964 | ISO | ISO 4049:2019 | 2019 | Dentistry -- Polymer-based restorative materials | 109 年度新增採認標準 |
| 203 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01965 | IEC | IEC 80601-2-60:2019 | 2019 | Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment | 109 年度新增採認標準 |
| 204 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01966 | ASA | ASA S3.22-2014 (R2020) | 2020 | Specification of Hearing Aid Characteristics | 109 年度新增採認標準 |
| 205 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01967 | IEC | IEC 60601-2-66:2019 | 2019 | Medical electrical equipment Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument system | 109 年度新增採認標準 |

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| 206 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00088 | ISO | ISO 10012:2003 | 2003 | Quality assurance requirements for measuring equipment Part 1: Metrological confirmation system for measuring equipment | 原採認標準 |
| 207 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00439 | CNS | CNS14991 | 2006 | 命名—用於醫療器材法規管理資料交換之命名系統的規格 | 原採認標準 |
| 208 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00440 | CNS | CNS14989 | 2006 | 醫療器材風險管理 | 原採認標準 |
| 209 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00441 | CNS | CNS14990 | 2006 | 醫療器材—用於醫療器材標識、標示與資訊之符號 | 原採認標準 |
| 210 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01013 | ISO | ISO 14155:2011/Cor1:2011 | 2011 | Clinical investigation of medical devices for human subjects -- Good clinical practice | 原採認標準 |
| 211 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01505 | AAMI | AAMI TIR69:2017 | 2017 | Risk management of radio-frequency wireless coexistence for medical devices and systems | 原採認標準 |
| 212 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01507 | EN | EN 45502-1:2015 | 2015 | Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer | 原採認標準 |
| 213 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01509 | IEC | IEC TR 80002-1:2009 | 2009 | Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software | 原採認標準 |

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| 214 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01510 | ISO | ISO 13485:2016 | 2016 | Medical devices — Quality management systems — Requirements for regulatory purposes | 原採認標準 |
| 215 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01511 | ISO | ISO 15223-1:2016 | 2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements | 原採認標準 |
| 216 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01512 | ISO | ISO 16061:2015 | 2015 | Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2015) | 原採認標準 |
| 217 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01513 | ISO | ISO 16142-1:2016 | 2016 | Medical devices-Recognized essential principles of safety and performance of medical devices-Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards | 原採認標準 |
| 218 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01514 | ISO | ISO 16142-2:2017 | 2017 | Medical devices - recognized essential principles of safety and performance of medical devices - part 2: generalESSENTIAL PRINCIPLES AND ADDITIONAL SPECIFIC ESSENTIAL PRINCIPLES FOR ALL IVD MEDICAL DEVICES AND GUIDANCE ON THE SELECTION OF STANDARDS | 原採認標準 |
| 219 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01517 | ISO | ISO 80369-6:2016 | 2016 | Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications | 原採認標準 |
| 220 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01518 | ISO | ISO/TS 19218-1/Amd1:2013 | 2013 | Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes AMENDMENT 1 - First Edition | 原採認標準 |

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| 221 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01797 | AAMI | AAMI TIR36:2007 | 2007 | Validation of software for regulated processes | 原採認標準 |
| 222 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01885 | AAMI | AAMI HE75:2009(R2018) | 2018 | Human factors engineering - Design of medical devices | 原採認標準 |
| 223 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01886 | ISO | IEC 80369-5:2016/COR 1:2017 | 2017 | Small-bore connectors for liquids and gases in healthcare applications—Part 5: Connectors for limb cuff inflation applications | 原採認標準 |
| 224 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01968 | ISO | ISO 14971:2019 | 2019 | Medical devices -- Application of risk management to medical devices | 109 年度新增採認標準 |
| 225 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01969 | ISO | ISO/TR 24971:2020 | 2020 | Medical devices — Guidance on the application of ISO 14971 | 109 年度新增採認標準 |
| 226 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01970 | IEC | IEC 62366-1:2015+AMD 1:2020 | 2020 | Medical devices –Part 1: Application of usability engineering to medical devices | 109 年度新增採認標準 |
| 227 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01971 | ISO | ISO 80369-3:2016/AMD 1:2019 | 2019 | Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications | 109 年度新增採認標準 |

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| 228 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00126 | ISO | ISO 8536-5:2004 | 2004 | Infusion Equipment for Medical Use - Part 5: Burette Type Infusion Sets | 原採認標準 |
| 229 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00298 | CNS | CNS 14775 | 2003 | 醫用面罩材料細菌過濾效率試驗法—使用金黃色葡萄球菌生物氣霧 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus | 原採認標準 |
| 230 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00463 | ISO | ISO 11608-4:2006 | 2006 | Pen-injectors for medical use – Part 4:Requirements and test methods for electronic and electromechanical pen-injectors | 原採認標準 |
| 231 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00464 | ISO | ISO 21649:2006 | 2006 | Needle-free injectors for medical use –Requirements and test methods | 原採認標準 |

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| 232 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00467 | ISO | ISO 8362-3:2001 | 2001 | Injection containers and accessories -- Part 3: Aluminium caps for injection vials | 原採認標準 |
| 233 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00471 | ISO | ISO 8362-7:2006 | 2006 | Injection containers and accessories –Part 7: Injection caps made of aluminiumplastics combinations without overlapping plastics part | 原採認標準 |
| 234 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00478 | CNS | CNS 4397 | 1999 | 脫脂紗布 | 原採認標準 |
| 235 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00589 | CNS | CNS 15036-1 | 2006 | 用於人類血液和血液成品塑膠可折疊之容器－第１部：慣用容器（血袋） | 原採認標準 |

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| 236 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00590 | CNS | CNS 13460: | 1994 | 電刀裝置 | 原採認標準 |
| 237 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00592 | CNS | CNS 14624-2 | 2002 | 醫療用輸液設備—第二部份：點滴瓶瓶塞 | 原採認標準 |
| 238 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00593 | CNS | CNS 14624-3 | 2002 | 醫療用輸液設備—第三部份：點滴瓶鋁蓋 | 原採認標準 |
| 239 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00599 | ISO | ISO 15883-2:2006 | 2006 | Washer-disinfectors -- Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. | 原採認標準 |

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| 240 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00600 | ISO | ISO 15883-3:2006 | 2006 | Washer-disinfectors -- Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers | 原採認標準 |
| 241 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00601 | ISO | ISO/TS 15883-5:2005 | 2005 | Washer-disinfectors -- Part 5: Test soils and methods for demonstrating cleaning efficacy | 原採認標準 |
| 242 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00784 | CNS | CNS 15042 | 2007 | 間歇性測定患者體溫之紅外線體溫計 | 原採認標準 |
| 243 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00785 | CNS | CNS 15043 | 2007 | 間歇性測定患者體溫之電子式體溫計 | 原採認標準 |

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| 244 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00786 | CNS | CNS 15044 | 2007 | 體溫計探針護套 | 原採認標準 |
| 245 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00787 | CNS | CNS 15212-3 | 2008 | 電子體溫計－第 3 部：具最大值（非預測性與預測性）裝置之小型電子體溫計的性能 | 原採認標準 |
| 246 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00788 | CNS | CNS 15212-4 | 2008 | 電子體溫計－第 4 部：用於連續量測之電子體溫計的性能 | 原採認標準 |
| 247 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00789 | CNS | CNS 15212-5 | 2008 | 電子體溫計－第 5 部：紅外線耳溫計（具最大值裝置）的性能 | 原採認標準 |

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| 248 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00790 | CNS | CNS 15226 | 2009 | 單次使用之無菌橡膠手套－規格 | 原採認標準 |
| 249 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00791 | CNS | CNS 15227 | 2009 | 單次使用之醫用檢驗手套－第 1 部：以乳膠或橡膠溶液製成之手套規格 | 原採認標準 |
| 250 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00917 | ISO | ISO 8536-2:2010 | 2010 | Infusion equipment for medical use -- Part 2: Closures for infusion bottles | 原採認標準 |
| 251 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00918 | ISO | ISO 8536-3:2009 | 2009 | Infusion equipment for medical use -- Part 3: Aluminium caps for infusion bottles | 原採認標準 |

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| 252 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00920 | ISO | ISO 8536-7:2009 | 2009 | Infusion equipment for medical use -- Part 7: Caps made of aluminium-plastics combinations for infusion bottles | 原採認標準 |
| 253 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00928 | ISO | ISO 8362-6:2010 | 2016 | Injection containers and accessories -- Part 6: Caps made of aluminium-plastics combinations for injection vials | 原採認標準 |
| 254 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00988 | OIML | OIML R115:1995 | 1995 | Clinical electrical thermometers with maximum device | 原採認標準 |
| 255 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01257 | AAMI | ANSI/AAMI BF7:2012 | 2012 | Blood transfusion micro-filters | 原採認標準 |

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| 256 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01259 | AAMI | AAMI PB70:2012 | 2012 | Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities | 原採認標準 |
| 257 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01272 | ASTM | ASTM F1671/F1671M-13 | 2013 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System | 原採認標準 |
| 258 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01275 | ASTM | ASTM F2119-07(2013) | 2013 | Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants | 原採認標準 |
| 259 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01276 | ASTM | ASTM F2172-02/(R)2011 | 2011 | Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers | 原採認標準 |

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| 260 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01281 | ASTM | ASTM F86-13 | 2013 | Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants | 原採認標準 |
| 261 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01283 | CEN | EN 13726-1:2002 | 2002 | Test methods for primary wound dressings - Part 1: Aspects of absorbency | 原採認標準 |
| 262 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01287 | CNS | CNS 14755 | 2011 | 拋棄式防塵口罩 (Disposable dust respirators) | 原採認標準 |
| 263 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01288 | CNS | CNS 14778 | 2003 | 防護衣詞彙 (Terminology relating to protective clothing) (IDE ASTM F1494-01) | 原採認標準 |

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| 264 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01289 | CNS | CNS 14798 | 2004 | 拋棄式醫用防護衣—性能要求(The performance requirements for disposable medical protective clothing) | 原採認標準 |
| 265 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01290 | CNS | CNS 14799 | 2004 | 防護衣材料對合成血液穿透阻力試驗法 (Method of test for resistance of materials used in protective clothing to penetration by synthetic blood) (IDE ASTM F1670-98) | 原採認標準 |
| 266 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01291 | CNS | CNS 14800 | 2004 | 使用 Phi-X174 噬菌體穿透力之試驗系統供防護衣材料對血液媒介病原穿透阻力的試驗法(Method of test for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system) (IDE AATCC 42-2000) | 原採認標準 |
| 267 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01292 | CNS | CNS 14801 | 2004 | 防護衣材料防水性試驗法－衝擊穿透試驗(Method of test for water resistance of material used in protective clothing (Impact penetration test)) | 原採認標準 |

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| 268 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01293 | CNS | CNS 15554 | 2012 | 醫電設備電性安全－第 2-52 部：醫護床基本安全及必要性能的特殊要求 (Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds) (IDE IEC 60601-2-52:2010) | 原採認標準 |
| 269 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01294 | IEC | IEC 60601-2-24:2012 | 2012 | Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers | 原採認標準 |
| 270 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01295 | IEC | IEC 60601-2-41:2009+AMD1:2013 | 2013 | Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis - Edition 2.1 | 原採認標準 |
| 271 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01301 | ISO | ISO 10555-3:2013 | 2013 | Intravascular catheters -- Sterile and single-use catheters -- Part 3: Central venous catheters | 原採認標準 |

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| 272 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01302 | ISO | ISO 10555-5:2013 | 2013 | Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters | 原採認標準 |
| 273 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01305 | ISO | ISO 11608-2:2012 | 2012 | Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles | 原採認標準 |
| 274 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01306 | ISO | ISO 11608-3:2012 | 2012 | Needle-based injection systems for medical use -- Requirements and test methods -- Part 3: Finished containers | 原採認標準 |
| 275 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01307 | ISO | ISO 7740:1985 | 1985 | Instruments for surgery, scalpels with detachable blades, fitting dimensions | 原採認標準 |

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| 276 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01309 | ISO | ISO 8362-4:2011 | 2011 | Injection containers and accessories -- Part 4: Injection vials made of moulded glass | 原採認標準 |
| 277 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01310 | ISO | ISO 8536-1:2011 | 2011 | Infusion equipment for medical use — Part 1: Infusion glass bottles - Fourth Edition | 原採認標準 |
| 278 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01312 | ISO | ISO 9187-1:2010 | 2010 | Injection equipment for medical use -- Part 1: Ampoules for injectables | 原採認標準 |
| 279 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01320 | ISO | ISO 10282:2014 | 2014 | Single-use sterile rubber surgical gloves - Specification - Third Edition | 原採認標準 |

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| 280 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01520 | ASTM | ASTM D7160-16 | 2016 | Standard Practice for Determination of Expiration Dating for Medical Gloves | 原採認標準 |
| 281 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01521 | ASTM | ASTM D7161-16 | 2016 | Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions | 原採認標準 |
| 282 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01523 | ASTM | ASTM F2051-00/(R)2014 | 2014 | Standard Specification for Implantable Saline Filled Breast Prosthesis | 原採認標準 |
| 283 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01528 | EN | EN 1865-1:2010+A1:2015 | 2015 | Patient handling equipment used in road ambulances Part 1: General stretcher systems and patient handling equipmen | 原採認標準 |

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| 284 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01529 | EN | EN 1865-2:2010+A1:2015 | 2015 | Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher | 原採認標準 |
| 285 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01530 | EN | EN 1865-3:2012+A1:2015 | 2015 | Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher | 原採認標準 |
| 286 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01531 | EN | EN 455-2:2015 | 2015 | Medical gloves for single use. Requirements and testing for physical properties | 原採認標準 |
| 287 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01532 | EN | EN 455-3:2015 | 2015 | Medical gloves for single use. Requirements and testing for biological evaluation | 原採認標準 |

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| 288 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01534 | IEC | IEC 60601-2-20:2009+AMD1:2016 | 2016 | Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators | 原採認標準 |
| 289 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01535 | IEC | IEC 60601-2-21:2009+AMD1:2016 | 2016 | Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers - Edition 2.1 | 原採認標準 |
| 290 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01536 | IEC | IEC 60601-2-46:2016 | 2016 | Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables | 原採認標準 |
| 291 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01537 | IEC | IEC 60601-2-50:2009+AMD1:2016 | 2016 | Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment | 原採認標準 |

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| 292 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01538 | IEC | IEC 60601-2-52:2009+AMD1:2015 | 2015 | Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds | 原採認標準 |
| 293 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01539 | IEC | IEC 80601-2-35:2009+AMD1:2016 | 2016 | Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use | 原採認標準 |
| 294 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01542 | ISO | ISO 1135-4:2015 | 2015 | Transfusion equipment for medical use Part 4: Transfusion sets for single use, gravity feed | 原採認標準 |
| 295 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01543 | ISO | ISO 11608-5:2012 | 2012 | Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions | 原採認標準 |

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| 296 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01544 | ISO | ISO 15883-1:2006/Amd1: 2014 | 2014 | Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests | 原採認標準 |
| 297 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01545 | ISO | ISO 3826-4 :2015 | 2015 | Plastics collapsible containers for human blood and blood components Part 4: Aphaeresis blood bag systems with integrated features | 原採認標準 |
| 298 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01546 | ISO | ISO 6009:2016 | 2016 | Hypodermic needles for single use - Colour coding for identification | 原採認標準 |
| 299 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01547 | ISO | ISO 7864:2016 | 2016 | Sterile hypodermic needles for single use — Requirements and test methods | 原採認標準 |

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| 300 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01548 | ISO | ISO 80369-20:2015 | 2015 | Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods | 原採認標準 |
| 301 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01551 | ISO | ISO 8362-2:2015 | 2015 | Injection containers and accessories - Part 2: Closures for injection vials | 原採認標準 |
| 302 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01552 | ISO | ISO 8362-5:2016 | 2016 | Injection containers and accessories - Part 5: Freeze drying closures for injection vials | 原採認標準 |
| 303 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01553 | ISO | ISO 8536-10:2015 | 2015 | Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment (ISO 8536-10:2015) | 原採認標準 |

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| 304 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01554 | ISO | ISO 8536-11:2015 | 2015 | Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment (ISO 8536-11:2015) | 原採認標準 |
| 305 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01555 | ISO | ISO 8536-6:2016 | 2016 | Infusion equipment for medical use - Part 6: Freeze drying closures for infusion bottles | 原採認標準 |
| 306 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01556 | ISO | ISO 8536-8:2015 | 2015 | Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus (ISO 8536-8:2015) | 原採認標準 |
| 307 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01557 | ISO | ISO 8536-9:2015 | 2015 | Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment (ISO 8536-9:2015) | 原採認標準 |

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| 308 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01558 | ISO | ISO 8537:2016 | 2016 | Sterile single-use syringes, with or without needle, for insulin | 原採認標準 |
| 309 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01559 | ISO | ISO 9626:2016 | 2016 | Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods | 原採認標準 |
| 310 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01799 | ASTM | ASTM F703-18 | 2018 | Standard Specification for Implantable Breast Prostheses | 原採認標準 |
| 311 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01800 | CNS | CNS 14774 | 2018 | 醫用面(口)罩 | 原採認標準 |

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| 312 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01801 | IEC | IEC 60601-2-19:2009+AMD1:2016 | 2016 | Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators | 原採認標準 |
| 313 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01802 | IEC | IEC 80601-2-59:2017 | 2017 | Medical electrical equipment -- Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening | 原採認標準 |
| 314 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01803 | ISO | ISO 10555-1:2013/AMD 1:2017 | 2017 | Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements | 原採認標準 |
| 315 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01804 | ISO | ISO 7886-1:2017 | 2017 | Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use | 原採認標準 |

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| 316 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01875 | ISO | ISO 21171:2006 | 2006 | Medical gloves Determination of removable surface powder | 原採認標準 |
| 317 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01887 | ASTM | ASTM F881 - 94(2014) | 2014 | Standard Specification for Silicone Elastomer Facial Implants | 原採認標準 |
| 318 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01888 | ASTM | ASTM F1441 - 03(2014) | 2014 | Standard Specification for Soft-Tissue Expander Devices | 原採認標準 |
| 319 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01889 | ASTM | ASTM F754 - 08(2015) | 2015 | Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders | 原採認標準 |

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| 320 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01890 | ASTM | ASTM E1104 - 98(2016) | 2016 | Standard Specification for Clinical Thermometer Probe Covers and Sheaths | 原採認標準 |
| 321 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01891 | ASTM | ASTM E1965 - 98(2016) | 2016 | Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature | 原採認標準 |
| 322 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01892 | AAMI | AAMI BP22:1994/(R2016) | 2016 | Blood pressure transducers | 原採認標準 |
| 323 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01893 | ASTM | ASTM D6124 - 06(2017) | 2017 | Standard Test Method for Residual Powder on Medical Gloves | 原採認標準 |

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| 324 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01894 | ASTM | ASTM D6355 - 07(2017) | 2017 | Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves | 原採認標準 |
| 325 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01895 | ASTM | ASTM E1112 - 00(2018) | 2018 | Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature | 原採認標準 |
| 326 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01896 | ISO | ISO 80601-2-56:2017/AMD 1:2018 | 2018 | Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement | 原採認標準 |
| 327 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01897 | ASTM | ASTM F1670 / F1670M - 17a | 2017 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood | 原採認標準 |

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| 328 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01898 | ISO | ISO 11193-1:2008/AMD 1:2012 | 2012 | Single-Use Medical Examination Gloves - Part 1: Specification for Gloves Made from Rubber Latex or Rubber Solution | 原採認標準 |
| 329 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01972 | CEN | EN 13795-1:2019 | 2019 | Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns | 109 年度新增採認標準 |
| 330 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01973 | CEN | EN 13795-2:2019 | 2019 | Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits | 109 年度新增採認標準 |
| 331 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01974 | ASTM | ASTM F1580-18 | 2018 | Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants | 109 年度新增採認標準 |

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| 332 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01975 | ASTM | ASTM F2213-17 | 2017 | Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment | 109 年度新增採認標準 |
| 333 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01976 | ASTM | ASTM F75-18 | 2018 | Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075) | 109 年度新增採認標準 |
| 334 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01977 | ASTM | ASTM D6499-18 | 2018 | Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products | 109 年度新增採認標準 |
| 335 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01978 | ASTM | ASTM D7169 - 20 | 2020 | Standard Test Method for Boiling Point Distribution of Samples with Residues Such as Crude Oils and Atmospheric and Vacuum Residues by High Temperature Gas Chromatography | 109 年度新增採認標準 |

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| 336 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01979 | EN | EN 14683:2019 | 2019 | Medical face masks - Requirements and test methods | 109 年度新增採認標準 |
| 337 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01980 | ISO | ISO 8362-1:2018 | 2018 | Injection containers and accessories - Part 1: Injection vials made of glass tubing | 109 年度新增採認標準 |
| 338 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01981 | ISO | ISO 7886-2:2020 | 2020 | Sterile Hypodermic Syringes for Single Use - Part 2: Syringes for use with Power-Driven Syringe Pumps | 109 年度新增採認標準 |
| 339 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01982 | ISO | ISO 7886-3:2020 | 2020 | Sterile hypodermic syringes for single use -- Part 3: Auto-disable syringes for fixed-dose immunization | 109 年度新增採認標準 |

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| 340 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01983 | CEN | EN 455-1:2020 | 2020 | Medical gloves for single use —Part 1: Requirements and testing for freedom from holes | 109 年度新增採認標準 |
| 341 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01984 | ASTM | ASTM D3577 - 19 | 2019 | Standard Specification for Rubber Surgical Gloves | 109 年度新增採認標準 |
| 342 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01985 | ASTM | ASTM D3578 - 19 | 2019 | Standard Specification for Rubber Examination Gloves | 109 年度新增採認標準 |
| 343 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01986 | ASTM | ASTM D5151 - 19 | 2019 | Standard Test Method for Detection of Holes in Medical Gloves | 109 年度新增採認標準 |

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| 344 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01987 | ASTM | ASTM D6978 - 05(2019) | 2019 | Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs | 109 年度新增採認標準 |
| 345 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01988 | ASTM | ASTM F2182 - 19e2 | 2019 | Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging | 109 年度新增採認標準 |
| 346 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01989 | ASTM | ASTM F2503 - 20 | 2020 | Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment | 109 年度新增採認標準 |
| 347 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01990 | ASTM | ASTM F899 - 20 | 2020 | Standard Specification for Wrought Stainless Steels for Surgical Instruments | 109 年度新增採認標準 |

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| 348 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01991 | ISO | ISO 8536-4:2019 | 2019 | Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed | 109 年度新增採認標準 |
| 349 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01992 | ASTM | ASTM A908 - 03(2019) | 2019 | Standard Specification for Stainless Steel Needle Tubing | 109 年度新增採認標準 |
| 350 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01993 | ASTM | ASTM D5250 - 19 | 2019 | Standard Specification for Poly(vinyl chloride) Gloves for Medical Application | 109 年度新增採認標準 |
| 351 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01994 | ASTM | ASTM F2710 - 19 | 2019 | Standard Consumer Safety Performance Specification for Commercial Cribs | 109 年度新增採認標準 |

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| 352 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01995 | ASTM | ASTM D6319 - 19 | 2019 | Standard Specification for Nitrile Examination Gloves for Medical Application | 109 年度新增採認標準 |
| 353 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00049 | CLSI | NCCLS GP14-A:1996 | 1996 | Labeling of Home-Use In Vitro Testing Products; Approved Guideline | 原採認標準 |
| 354 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00055 | CLSI | NCCLS NRSCL 8-A:1998 | 1998 | Terminology and Definitions for use in NCCLS Documents; Approved Standard | 原採認標準 |
| 355 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00175 | CLSI | C42-A | 1996 | Erythrocyte Protoporphyrin Testing; Approved Guideline (1996) | 原採認標準 |
| 356 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00188 | CLSI | H15-A3 | 2000 | Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition | 原採認標準 |
| 357 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00192 | CLSI | M15-A | 2000 | Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline | 原採認標準 |
| 358 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00204 | CLSI | C29-A2 | 2000 | Standardization of Sodium and Potassium Ion Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard (2000) | 原採認標準 |
| 359 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00205 | CLSI | C31-A2 | 2001 | Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline - Second Edition (2001) | 原採認標準 |
| 360 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00209 | CLSI | H07-A3 | 2000 | Procedure for Determining Packed Cell Volume by the Microhematocrit Method - Second Edition; Approved Standard - Third Edition | 原採認標準 |
| 361 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00210 | CLSI | H30-A2 | 2001 | Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline Second Edition | 原採認標準 |

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| 362 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00319 | CEN | EN 13612:2002 | 2002 | Performance evaluation of in vitro diagnostic medical devices | 原採認標準 |
| 363 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00321 | ISO | ISO 18153:2003 | 2003 | In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials | 原採認標準 |
| 364 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00324 | CLSI | I/LA23-A | 2004 | Assessing the Quality of Immunoassay Systems: Radioimmunoassays, and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guidelines | 原採認標準 |
| 365 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00328 | CLSI | H56-A | 2006 | Body fluid analysis for cellular composition | 原採認標準 |
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| 367 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00332 | CLSI | MM12-A | 2006 | Diagnostic nucleic acid microarrays | 原採認標準 |
| 368 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00333 | CLSI | C38-A | 1997 | Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline | 原採認標準 |
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| 370 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00336 | CLSI | C44-A | 2002 | Harmonization of Glycohemoglobin Measurements; Approved Guideline | 原採認標準 |
| 371 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00337 | CLSI | C45-A | 2004 | Measurement of Free Thyroid Hormones; - Approved Guideline | 原採認標準 |

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| 372 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00339 | CLSI | H45-A2 | 2005 | Performance of the Bleeding Time Test; Approved Guideline | 原採認標準 |
| 373 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00481 | CLSI | POCT01-A2 | 2006 | Point-of-Care Connectivity; Approved Standard- Second Edition | 原採認標準 |
| 374 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00494 | CLSI | C37-A | 1999 | Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline | 原採認標準 |
| 375 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00496 | CLSI | EP06-A | 2003 | Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline | 原採認標準 |
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| 377 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00512 | CLSI | MM13-A | 2006 | Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline | 原採認標準 |
| 378 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00646 | CLSI | H21-A5 | 2008 | Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - Fifth Edition | 原採認標準 |
| 379 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00647 | CLSI | I/LA21-A2 | 2008 | Clinical Evaluation of Immunoassays; Approved Guideline-Second Edition | 原採認標準 |
| 380 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00651 | CLSI | H20-A2 | 2007 | Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition | 原採認標準 |
| 381 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00652 | CLSI | H42-A2 | 2007 | Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline - Second Edition | 原採認標準 |
| 382 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00653 | CLSI | H43-A2 | 2007 | Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline - Second Edition | 原採認標準 |

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| 383 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00654 | CLSI | H44-A2 | 2004 | Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry and Supravital Dyes); Approved Guideline- Second Edition | 原採認標準 |
| 384 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00655 | CLSI | I/LA18-A2 | 2001 | Specifications for Immunological Testing for Infectious Diseases; Approved Guideline - Second Edition | 原採認標準 |
| 385 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00658 | CLSI | M28-A2 | 2005 | Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline - Second Edition | 原採認標準 |
| 386 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00661 | CLSI | EP12-A2 | 2008 | User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition | 原採認標準 |
| 387 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00667 | CLSI | GP20-A2 | 2003 | Fine-Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline-Second Edition | 原採認標準 |
| 388 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00832 | CLSI | EP18-A2 | 2009 | Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline-Second Edition | 原採認標準 |
| 389 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00834 | CLSI | GP16-A3 | 2009 | Urinalysis; Approved Guideline - Third Edition | 原採認標準 |
| 390 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00835 | CLSI | C46-A2 | 2009 | Blood Gas and pH Analysis and Related Measurements; Approved Guideline-Second Edition | 原採認標準 |
| 391 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00839 | CLSI | H26-A2 | 2010 | Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard-Second Edition | 原採認標準 |
| 392 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00840 | CLSI | M22-A3 | 2004 | Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard- Third Edition (2004) | 原採認標準 |
| 393 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00850 | CLSI | MM11-A | 2007 | Molecular Methods for Bacterial Strain Typing; Approved Guideline | 原採認標準 |

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| 394 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00851 | CLSI | C43-A2 | 2010 | Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline-Second Edition | 原採認標準 |
| 395 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00853 | CLSI | POCT02-A | 2008 | Implementation Guide of POCT01 for Health Care Providers; Approved Guideline | 原採認標準 |
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| 398 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00943 | CLSI | I/LA29-A | 2008 | Detection of HLA-Specific Alloantibody by Flow Cytometry and Solid Phase Assays; Approved Guideline | 原採認標準 |
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| 400 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00945 | CLSI | EP25-A | 2009 | Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline | 原採認標準 |
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| 402 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01108 | CLSI | C40-A2 | 2013 | Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline | 原採認標準 |
| 403 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01109 | CLSI | EP17-A2 | 2012 | Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition | 原採認標準 |
| 404 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01110 | CLSI | GP40-A4-AMD | 2012 | Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline, Fourth Edition | 原採認標準 |
| 405 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01111 | CLSI | GP42-A6 | 2008 | Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard--Sixth Edition | 原採認標準 |

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| 406 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01112 | CLSI | M39-A4 | 2014 | Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline - Fourth Edition; Vol. 34; No. 2 | 原採認標準 |
| 407 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01113 | CLSI | MM09-A2 | 2014 | Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline | 原採認標準 |
| 408 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01115 | CLSI | EP10-A3-AMD | 2014 | Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline - Third Edition | 原採認標準 |
| 409 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01116 | CLSI | EP24-A2 | 2011 | Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline - Second Edition | 原採認標準 |
| 410 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01117 | CLSI | EP28-A3C | 2010 | Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition | 原採認標準 |
| 411 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01119 | CLSI | GP39-A6 | 2010 | Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition | 原採認標準 |
| 412 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01120 | CLSI | I/LA25-A2 | 2011 | Maternal Serum Screening; Approved Standard, Second Edition | 原採認標準 |
| 413 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01127 | CLSI | MM01-A3 | 2012 | Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline | 原採認標準 |
| 414 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01128 | CLSI | MM05-A2 | 2012 | Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline-Second Edition,MM05A2E | 原採認標準 |
| 415 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01129 | CLSI | MM06-A2 | 2010 | Quantitative Molecular Methods for Infectious Diseases; Approved Guideline - Second Edition | 原採認標準 |
| 416 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01130 | CLSI | MM14-A2 | 2013 | Design of Molecular Proficiency Testing/External Quality Assessment; Approved Guideline—Second Edition | 原採認標準 |

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| 418 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01133 | CLSI | POCT14-A | 2004 | Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline | 原採認標準 |
| 419 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01134 | CLSI | QMS06-A3 | 2011 | Quality Management System: Continual Improvement; Approved Guideline - Third Edition; Vol 31; No 14 | 原採認標準 |
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| 421 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01138 | CLSI | GP34-A | 2010 | Validation and Verfication of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guidance | 原採認標準 |
| 422 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01139 | EN | EN 13532 | 2012 | General requirements for in vitro diagnostic medical devices for self-testing | 原採認標準 |
| 423 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01143 | IEC | IEC 61326-2-6:2012 ed2.0 | 2012 | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment - Edition 2.0 | 原採認標準 |
| 424 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01144 | ISO | ISO 15193:2009 | 2009 | In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures - Second Edition | 原採認標準 |
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| 427 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01147 | ISO | ISO 18113-1:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements - First Edition | 原採認標準 |
| 428 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01148 | ISO | ISO 18113-2:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use - First Edition | 原採認標準 |
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| 430 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01150 | ISO | ISO 18113-4:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing - First Edition | 原採認標準 |
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| 433 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01560 | CLSI | AUTO11-A2 | 2014 | Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard - Second Edition; Vol 34; No 17 | 原採認標準 |

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| 440 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01567 | CLSI | EP21 | 2016 | Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures | 原採認標準 |
| 441 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01568 | CLSI | I/LA20 | 2016 | Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities | 原採認標準 |
| 442 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01571 | CLSI | MM03 | 2015 | Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline | 原採認標準 |
| 443 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01572 | CLSI | MM21 | 2015 | Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications | 原採認標準 |
| 444 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01573 | CLSI | POCT04 | 2016 | Essential Tools for Implementation and Management of a Point-of-Care Testing Program - Third Edition | 原採認標準 |

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| 445 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01574 | CLSI | POCT13c | 2015 | Glucose Monitoring in Settings Without Laboratory Support | 原採認標準 |
| 446 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01578 | ISO | ISO 22870:2016 | 2016 | Point-of-care testing (POCT) - Requirements for quality and competence | 原採認標準 |
| 447 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01579 | ISO | ISO/TS 17822-1:2014 | 2014 | In vitro diagnostic test systems — Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens Part 1: General requirements, terms and definitions | 原採認標準 |
| 448 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01899 | CLSI | C49 | 2018 | Analysis of Body Fluids in Clinical Chemistry; Approved Guideline | 原採認標準 |
| 449 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01900 | CLSI | EP09c | 2018 | Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition | 原採認標準 |
| 450 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01901 | CLSI | M27 | 2017 | Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement | 原採認標準 |
| 451 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01902 | CLSI | VET01 | 2018 | Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard—Fourth Edition | 原採認標準 |
| 452 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01996 | CLSI | EP07 | 2018 | Interference Testing in Clinical Chemistry | 109 年度新增採認標準 |
| 453 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01997 | CLSI | M23 | 2018 | Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters | 109 年度新增採認標準 |
| 454 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01998 | CLSI | M02 | 2018 | Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard -Twelfth Edition | 109 年度新增採認標準 |
| 455 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01999 | CLSI | M07 | 2018 | Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard -Tenth Edition | 109 年度新增採認標準 |

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| 456 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02000 | CLSI | M11 | 2018 | Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard | 109 年度新增採認標準 |
| 457 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02001 | CLSI | M24 | 2018 | Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard | 109 年度新增採認標準 |
| 458 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02002 | ISO | ISO 6710:2017 | 2017 | Single-use containers for human venous blood specimen collection | 109 年度新增採認標準 |
| 459 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02003 | CLSI | M45 | 2016 | Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline | 109 年度新增採認標準 |
| 460 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02004 | IEC | IEC 61010-2-101:2018 | 2018 | Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101: Particular Requirements for in Vitro Diagnostic (IVD) Medical Equipment | 109 年度新增採認標準 |
| 461 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02005 | CLSI | QMS24 | 2016 | Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality | 109 年度新增採認標準 |
| 462 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02006 | CLSI | MM17 | 2018 | Validation and Verification of Multiplex Nucleic Acid Assays | 109 年度新增採認標準 |
| 463 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02007 | CLSI | MM23 | 2015 | Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms) | 109 年度新增採認標準 |
| 464 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02008 | ISO | ISO 17511:2020 | 2020 | In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials | 109 年度新增採認標準 |

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| 465 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02009 | ISO | ISO 20776-1:2019 | 2019 | Clinical laboratory testing and in vitro diagnostic test systems Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases - First Edition | 109 年度新增採認標準 |
| 466 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-02010 | IEC | IEC 61010-1:2010/AMD1:2016/COR1:2019 | 2019 | Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements | 109 年度新增採認標準 |
| 467 | 8 Materials 材料 | TFDA-00071 | ISO | ISO 5832-6:1997 | 1997 | Implants for surgery -- Metallic materials -- Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy | 原採認標準 |
| 468 | 8 Materials 材料 | TFDA-00394 | ISO | ISO 5832-5:2005 | 2005 | Implants for surgery -- Metallic materials -- Part 5: Wrought cobalt-chromium-tungsten-nickel alloy | 原採認標準 |
| 469 | 8 Materials 材料 | TFDA-00399 | ISO | ISO 16428:2005 | 2005 | Implants for surgery – Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices | 原採認標準 |
| 470 | 8 Materials 材料 | TFDA-00539 | CNS | CNS 13382-1 | 2004 | 外科體內植入物－金屬材料－鍛造不鏽鋼 | 原採認標準 |
| 471 | 8 Materials 材料 | TFDA-00540 | CNS | CNS 13382-2 | 2004 | 外科體內植入物－金屬材料－鍛造鈷－鉻－鎢－鎳合金 | 原採認標準 |
| 472 | 8 Materials 材料 | TFDA-00541 | CNS | CNS 13382-3 | 2004 | 外科體內植入物－金屬材料－鍛造鈷－鎳－鉻－鉬－鎢－鐵合金 | 原採認標準 |
| 473 | 8 Materials 材料 | TFDA-00542 | CNS | CNS 13382-4 | 2004 | 外科體內植入物－金屬材料－鍛造鈷－鎳－鉻－鉬合金 | 原採認標準 |
| 474 | 8 Materials 材料 | TFDA-00543 | CNS | CNS 13382-5 | 2004 | 外科體內植入物－金屬材料－鈦金屬 | 原採認標準 |
| 475 | 8 Materials 材料 | TFDA-00544 | CNS | CNS 13382-6 | 2004 | 外科體內植入物－金屬材料－鑄造鈷-鉻-鉬合金 | 原採認標準 |
| 476 | 8 Materials 材料 | TFDA-00545 | CNS | CNS 13382-7 | 2004 | 外科體內植入物－金屬材料－鍛造鈦－６鋁－４釩合金 | 原採認標準 |
| 477 | 8 Materials 材料 | TFDA-00546 | CNS | CNS 13382-8 | 2004 | 外科體內植入物－金屬材料－可鍛及冷作加工鈷－鉻－鎳－鉬－鐵合金 | 原採認標準 |

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| 478 | 8 Materials 材料 | TFDA-00955 | CEN | EN 29073-3:1992 | 1992 | Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation | 原採認標準 |
| 479 | 8 Materials 材料 | TFDA-00957 | ISO | ISO 9073-10:2003 | 2003 | Textiles -- Test methods for nonwovens -- Part 10: Lint and other particles generation in the dry state | 原採認標準 |
| 480 | 8 Materials 材料 | TFDA-01091 | ASTM | ASTM F1713-08/(R)2013 | 2013 | Standard Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130) | 原採認標準 |
| 481 | 8 Materials 材料 | TFDA-01096 | ASTM | ASTM F562-13 | 2012 | Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035) | 原採認標準 |
| 482 | 8 Materials 材料 | TFDA-01099 | ISO | ISO 139:2005/Amd 1:2011 | 2011 | Textiles -- Standard atmospheres for conditioning and testing | 原採認標準 |
| 483 | 8 Materials 材料 | TFDA-01581 | ASTM | ASTM D3772-15 | 2015 | Standard Specification for Industrial Rubber Finger Cots | 原採認標準 |
| 484 | 8 Materials 材料 | TFDA-01583 | ASTM | ASTM F1185-03/(R)2014 | 2014 | Standard Specification for Composition of Hydroxylapatite for Surgical Implants | 原採認標準 |
| 485 | 8 Materials 材料 | TFDA-01584 | ASTM | ASTM F136-13 | 2013 | Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) | 原採認標準 |
| 486 | 8 Materials 材料 | TFDA-01588 | ASTM | ASTM F2224-09/(R)2014 | 2014 | Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants | 原採認標準 |
| 487 | 8 Materials 材料 | TFDA-01590 | ASTM | ASTM F2347-15 | 2015 | Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications | 原採認標準 |

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| 488 | 8 Materials 材料 | TFDA-01591 | ASTM | ASTM F2565-13 | 2013 | Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications | 原採認標準 |
| 489 | 8 Materials 材料 | TFDA-01592 | ASTM | ASTM F2695-12 | 2012 | Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications | 原採認標準 |
| 490 | 8 Materials 材料 | TFDA-01593 | ASTM | ASTM F2820-12 | 2012 | Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications | 原採認標準 |
| 491 | 8 Materials 材料 | TFDA-01594 | ASTM | ASTM F2971-13 | 2013 | Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing | 原採認標準 |
| 492 | 8 Materials 材料 | TFDA-01595 | ASTM | ASTM F3087-15 | 2015 | Standard Specification for Acrylic Molding Resins for Medical Implant Applications | 原採認標準 |
| 493 | 8 Materials 材料 | TFDA-01596 | ISO | ISO 13356:2015 | 2015 | Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia (Y–TZP). | 原採認標準 |
| 494 | 8 Materials 材料 | TFDA-01597 | ISO | ISO 14708-1:2014 | 2014 | Implants for surgery — Active implantable medical devices —Part 1: General requirements for safety, marking and for information to be provided by the manufacturer | 原採認標準 |
| 495 | 8 Materials 材料 | TFDA-01598 | ISO | ISO 5832-1:2016 | 2016 | Implants for surgery - Metallic materials - Part 1: Wrought stainless steel | 原採認標準 |
| 496 | 8 Materials 材料 | TFDA-01599 | ISO | ISO 5832-11:2014 | 2014 | Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy | 原採認標準 |
| 497 | 8 Materials 材料 | TFDA-01600 | ISO | ISO 5832-3:2016 | 2016 | Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy | 原採認標準 |
| 498 | 8 Materials 材料 | TFDA-01601 | ISO | ISO 5832-4:2014 | 2014 | Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy - Third Edition | 原採認標準 |

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| 499 | 8 Materials 材料 | TFDA-01602 | ISO | ISO 5832-7:2016 | 2016 | Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobaltchromium- nickel-molybdenum-iron alloy | 原採認標準 |
| 500 | 8 Materials 材料 | TFDA-01603 | ISO | ISO/ASTM 52900:2015 | 2015 | Standard Terminology for Additive Manufacturing – General Principles – Terminology | 原採認標準 |
| 501 | 8 Materials 材料 | TFDA-01604 | ISO | ISO/ASTM 52921:2013 | 2013 | Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies | 原採認標準 |
| 502 | 8 Materials 材料 | TFDA-01805 | ASTM | ASTM D412-16 | 2016 | Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension | 原採認標準 |
| 503 | 8 Materials 材料 | TFDA-01806 | ASTM | ASTM F1925-17 | 2017 | Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants | 原採認標準 |
| 504 | 8 Materials 材料 | TFDA-01807 | ASTM | ASTM F2026-17 | 2017 | Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications | 原採認標準 |
| 505 | 8 Materials 材料 | TFDA-01808 | ASTM | ASTM F2052-15 | 2015 | Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment | 原採認標準 |
| 506 | 8 Materials 材料 | TFDA-01810 | ASTM | ASTM F2459-18 | 2018 | Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis | 原採認標準 |
| 507 | 8 Materials 材料 | TFDA-01813 | ISO | ISO 10974:2018 | 2018 | Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device | 原採認標準 |
| 508 | 8 Materials 材料 | TFDA-01814 | ISO | ISO 5832-2:2018 | 2018 | Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium | 原採認標準 |
| 509 | 8 Materials 材料 | TFDA-01815 | ISO | ISO/ASTM 52901:2017 | 2017 | Standard Guide for Additive Manufacturing—General Principles—Requirements for Purchased AM Parts | 原採認標準 |
| 510 | 8 Materials 材料 | TFDA-01903 | AAMI | AAMI ST65:2008 (R2018) | 2018 | Processing of reusable surgical textiles for use in health care facilities | 原採認標準 |

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| 511 | 8 Materials 材料 | TFDA-01904 | ASTM | ASTM F2393 - 12(2016) | 2016 | Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications | 原採認標準 |
| 512 | 8 Materials 材料 | TFDA-01905 | ASTM | ASTM F621 - 12(2017) | 2017 | Standard Specification for Stainless Steel Forgings for Surgical Implants | 原採認標準 |
| 513 | 8 Materials 材料 | TFDA-01906 | ASTM | ASTM F1581 - 08(2016) | 2016 | Standard Specification for Composition of Anorganic Bone for Surgical Implants | 原採認標準 |
| 514 | 8 Materials 材料 | TFDA-01907 | ASTM | ASTM F3260 - 18 | 2018 | Standard Test Method for Determining the Flexural Stiffness of Medical Textiles | 原採認標準 |
| 515 | 8 Materials 材料 | TFDA-02011 | ISO | ISO 5834-3:2019 | 2019 | Implants for surgery – Ultra-high molecular-weight polyethylene – Part 3:Accelerated ageing methods | 109 年度新增採認標準 |
| 516 | 8 Materials 材料 | TFDA-02012 | ISO | ISO 5834-4:2019 | 2019 | Implants for surgery – Ultra-high molecular-weight polyethylene – Part 4:Oxidation index measurement method | 109 年度新增採認標準 |
| 517 | 8 Materials 材料 | TFDA-02013 | ISO | ISO 5834-5:2019 | 2019 | Implants for surgery – Ultra-high molecular-weight polyethylene – Part 5:Morphology assessment method | 109 年度新增採認標準 |
| 518 | 8 Materials 材料 | TFDA-02014 | ISO | ISO 5832-9:2019 | 2019 | Implants for surgery -- Metallic materials -- Part 9:Wrought high nitrogen stainless steel | 109 年度新增採認標準 |
| 519 | 8 Materials 材料 | TFDA-02015 | ISO | ISO 5832-12:2019 | 2019 | Implants for surgery -- Metallic materials -- Part 12:Wrought cobalt-chromium-molybdenum alloy | 109 年度新增採認標準 |
| 520 | 8 Materials 材料 | TFDA-02016 | ISO | ISO 5834-1:2019 | 2019 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 1:Powder form | 109 年度新增採認標準 |
| 521 | 8 Materials 材料 | TFDA-02017 | ISO | ISO 6474-1:2019 | 2019 | Implants for surgery -- Ceramic materials -- Part 1:Ceramic materials based on high purity alumina | 109 年度新增採認標準 |
| 522 | 8 Materials 材料 | TFDA-02018 | ISO | ISO 811:2018 | 2018 | Textiles - Determination of resistance to water penetration - Hydrostatic pressure test | 109 年度新增採認標準 |

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| 523 | 8 Materials 材料 | TFDA-02019 | ASTM | ASTM F2063-18 | 2018 | Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants | 109 年度新增採認標準 |
| 524 | 8 Materials 材料 | TFDA-02020 | ISO | ISO 5834-2:2019 | 2019 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 2: Moulded forms | 109 年度新增採認標準 |
| 525 | 8 Materials 材料 | TFDA-02021 | ASTM | ASTM F2313-18 | 2018 | Standard Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide | 109 年度新增採認標準 |
| 526 | 8 Materials 材料 | TFDA-02022 | ASTM | ASTM F3268-18a | 2018 | Standard Guide for in vitro Degradation Testing of Absorbable Metals | 109 年度新增採認標準 |
| 527 | 8 Materials 材料 | TFDA-02023 | ISO | ISO/ASTM 52910-18 | 2018 | Additive manufacturing - Design - Requirements, guidelines and recommendations | 109 年度新增採認標準 |
| 528 | 8 Materials 材料 | TFDA-02024 | ASTM | ASTM F3301-18a | 2018 | Standard for Additive Manufacturing—Post Processing Methods—Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion. | 109 年度新增採認標準 |
| 529 | 8 Materials 材料 | TFDA-02025 | ASTM | ASTM F3302-18 | 2018 | Standard for Additive Manufacturing—Finished Part Properties—Standard Specification for Titanium Alloys via Powder Bed Fusion | 109 年度新增採認標準 |
| 530 | 8 Materials 材料 | TFDA-02026 | ISO/ASTM | ISO/ASTM 52904:2019 | 2019 | Standard for Additive Manufacturing—Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications. | 109 年度新增採認標準 |
| 531 | 8 Materials 材料 | TFDA-02027 | ISO | ISO 13782:2019 | 2019 | Implants for surgery -- Metallic materials -- Unalloyed tantalum for surgical implant applications | 109 年度新增採認標準 |
| 532 | 8 Materials 材料 | TFDA-02028 | ISO | ISO 13938-1:2019 | 2019 | Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension | 109 年度新增採認標準 |

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| 533 | 8 Materials 材料 | TFDA-02029 | ASTM | ASTM F1091 - 20 | 2020 | Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605) | 109 年度新增採認標準 |
| 534 | 8 Materials 材料 | TFDA-02030 | ASTM | ASTM F139 - 19 | 2019 | Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673) | 109 年度新增採認標準 |
| 535 | 8 Materials 材料 | TFDA-02031 | ASTM | ASTM F1537 - 20 | 2020 | Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) | 109 年度新增採認標準 |
| 536 | 8 Materials 材料 | TFDA-02032 | ASTM | ASTM F2129 - 19a | 2019 | Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices | 109 年度新增採認標準 |
| 537 | 8 Materials 材料 | TFDA-02033 | ASTM | ASTM F3208 - 19 | 2019 | Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices. | 109 年度新增採認標準 |
| 538 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00878 | IEC | IEC 60601-2-18 ed3.0 : 2009 | 2009 | Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment | 原採認標準 |
| 539 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01252 | CNS | CNS 14194 | 1998 | 血液透析器、血液過濾器、血液濃縮器之體外迴路管 (Extracorporeal blood circuit for haemodialysers hasmofilters and haemoconcentrators) | 原採認標準 |

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| 540 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01325 | CNS | CNS 6629 | 2007 | 天然乳膠衛生套 (Natural latex rubber condoms - Requirements and test methods)(IDT: ISO 4074:2015) | 原採認標準 |
| 541 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01605 | ASTM | ASTM D1894-14 | 2014 | Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting | 原採認標準 |
| 542 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01607 | ISO | ISO 4074:2015 | 2015 | Natural latex rubber condoms - Requirements and test methods | 原採認標準 |
| 543 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01608 | ISO | ISO 7439:2015 | 2015 | Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2015) | 原採認標準 |
| 544 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01609 | ISO | ISO 8009:2014 | 2014 | Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests | 原採認標準 |
| 545 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01610 | ISO | ISO 8637-1:2017 | 2017 | Extracorporeal systems for blood purification -- Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators | 原採認標準 |

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| 546 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01763 | ASTM | ASTM F1828-17 | 2017 | Standard Specification for Ureteral Stents | 原採認標準 |
| 547 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01816 | IEC | IEC 60601-2-16:2018 | 2018 | Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment. | 原採認標準 |
| 548 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01817 | ISO | ISO 29943-1:2017 | 2017 | Condoms—Guidance on clinical studies—Part 1: Male condoms, clinical function studies based on self-reports | 原採認標準 |
| 549 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01818 | ISO | ISO 29943-2:2017 | 2017 | Condoms—Guidance on clinical studies—Part 2: Female condoms, clinical function studies | 原採認標準 |
| 550 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02034 | ISO | ISO 8637-2:2018 | 2018 | Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters | 109 年度新增採認標準 |
| 551 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02035 | ISO | ISO 23500-3:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies | 109 年度新增採認標準 |

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| 552 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02036 | ISO | ISO 23500-2:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies | 109 年度新增採認標準 |
| 553 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02037 | AAMI | AAMI/ISO 23500-1:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements | 109 年度新增採認標準 |
| 554 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02038 | EN | ISO 20695:2020 | 2020 | Enteral feeding systems — Design and testing | 109 年度新增採認標準 |
| 555 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02039 | ISO | ISO 23500-5:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies | 109 年度新增採認標準 |
| 556 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02040 | ISO | ISO 23500-4:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies | 109 年度新增採認標準 |
| 557 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02041 | ISO | ISO 8600-3:2019 | 2019 | Endoscopes — Medical endoscopes and endotherapy devices —Part 3: Determination of field of view and direction of view of endoscopes with optics | 109 年度新增採認標準 |

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| 558 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-02042 | AAMI | AAMI RD47-2020 | 2020 | Reprocessing of hemodialyzers | 109 年度新增採認標準 |
| 559 | 10 Ophthalmic 眼科學 | TFDA-00990 | CNS | CNS 12446 | 1988 | 軟性隱形眼鏡片 | 原採認標準 |
| 560 | 10 Ophthalmic 眼科學 | TFDA-00995 | ISO | ISO 8980-4:2006 | 2006 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 4: Specifications and test methods for anti-reflective coatings | 原採認標準 |
| 561 | 10 Ophthalmic 眼科學 | TFDA-00996 | ISO | ISO 8980-5:2005 | 2005 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant | 原採認標準 |
| 562 | 10 Ophthalmic 眼科學 | TFDA-01327 | CNS | CNS 15448-1 | 2011 | 眼科光學－未切邊之眼鏡鏡片成品－第 1 部：單光與多焦點眼鏡鏡片規格 (Ophthalmic optics - Uncut finished spectacle lenses - Part 1: Specifications for single-vision and multifocal lenses)(IDT: ISO 8980-1:2004) | 原採認標準 |
| 563 | 10 Ophthalmic 眼科學 | TFDA-01328 | CNS | CNS 15448-2 | 2011 | 眼科光學－未切邊之眼鏡鏡片成品－第 2 部：漸進多焦點眼鏡鏡片規格 (Ophthalmic optics - Uncut finished spectacle lenses - Part 2: Specifications for progressive lenses) (IDT: ISO 8980-2:2004) | 原採認標準 |
| 564 | 10 Ophthalmic 眼科學 | TFDA-01331 | ISO | ISO 10936-2:2010 | 2010 | Optics and photonics -- Operation microscopes -- Part 2: Light hazard from operation microscopes used in ocular surgery | 原採認標準 |
| 565 | 10 Ophthalmic 眼科學 | TFDA-01335 | ISO | ISO 11979-3:2012 | 2012 | Ophthalmic Implants - Intraocular Lenses - Part 3: Mechanical Properties and Test Methods - Third Edition | 原採認標準 |
| 566 | 10 Ophthalmic 眼科學 | TFDA-01336 | ISO | ISO 11979-5:2006 | 2006 | Ophthalmic Implants - Intraocular Lenses - Part 5: Biocompatibility - Second Edition | 原採認標準 |

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| 567 | 10 Ophthalmic 眼科學 | TFDA-01341 | ISO | ISO 11987:2012 | 2012 | Ophthalmic optics -- Contact lenses -- Determination of shelf-life | 原採認標準 |
| 568 | 10 Ophthalmic 眼科學 | TFDA-01342 | ISO | ISO 14534:2011 | 2011 | Ophthalmic optics -- Contact lenses and contact lens care products -- Fundamental requirements | 原採認標準 |
| 569 | 10 Ophthalmic 眼科學 | TFDA-01344 | ISO | ISO 8980-3:2013 | 2013 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 3: Transmittance specifications and test methods | 原採認標準 |
| 570 | 10 Ophthalmic 眼科學 | TFDA-01345 | ISO | ISO 9394:2012 | 2012 | Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of biocompatibility by ocular study with rabbit eyes | 原採認標準 |
| 571 | 10 Ophthalmic 眼科學 | TFDA-01346 | ANSI | ANSI Z80.7, 2013 | 2013 | Ophthalmic Optics – Intraocular Lenses | 原採認標準 |
| 572 | 10 Ophthalmic 眼科學 | TFDA-01611 | ISO | ISO 18189:2016 | 2016 | Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/ solution interactions | 原採認標準 |
| 573 | 10 Ophthalmic 眼科學 | TFDA-01612 | ANSI | ANSI Z80.36-2016 | 2016 | Ophthalmics – Light Hazard Protection for Ophthalmic Instruments | 原採認標準 |
| 574 | 10 Ophthalmic 眼科學 | TFDA-01615 | ISO | ISO 11979-2:2014 | 2014 | Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods - Second Edition | 原採認標準 |
| 575 | 10 Ophthalmic 眼科學 | TFDA-01616 | ISO | ISO 14730:2014 | 2014 | Ophthalmic optics -- Contact lens care products -- Antimicrobial preservative efficacy testing and guidance on determining discard date | 原採認標準 |
| 576 | 10 Ophthalmic 眼科學 | TFDA-01819 | IEC | IEC 80601-2-58:2016 | 2016 | Medical electrical equipment - Part 2-58: Particular requirementsfor the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery | 原採認標準 |
| 577 | 10 Ophthalmic 眼科學 | TFDA-01820 | ISO | ISO 10936-1:2017 | 2017 | Optics and photonics - Operation microscopes - Part 1: Requirements and test methods | 原採認標準 |

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| 578 | 10 Ophthalmic 眼科學 | TFDA-01821 | ISO | ISO 11979-10:2018 | 2018 | Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes | 原採認標準 |
| 579 | 10 Ophthalmic 眼科學 | TFDA-01823 | ISO | ISO 11979-8:2018 | 2017 | Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements | 原採認標準 |
| 580 | 10 Ophthalmic 眼科學 | TFDA-01824 | ISO | ISO 11981:2017 | 2017 | Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses | 原採認標準 |
| 581 | 10 Ophthalmic 眼科學 | TFDA-01825 | ISO | ISO 11986:2017 | 2017 | Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release | 原採認標準 |
| 582 | 10 Ophthalmic 眼科學 | TFDA-01826 | ISO | ISO 15798:2013+A1:2017 | 2017 | Ophthalmic implants—Ophthalmic viscosurgical devices | 原採認標準 |
| 583 | 10 Ophthalmic 眼科學 | TFDA-01827 | ISO | ISO 18369-1:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications | 原採認標準 |
| 584 | 10 Ophthalmic 眼科學 | TFDA-01828 | ISO | ISO 18369-2:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 2: Tolerances | 原採認標準 |
| 585 | 10 Ophthalmic 眼科學 | TFDA-01829 | ISO | ISO 18369-3:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 3: Measurement methods | 原採認標準 |
| 586 | 10 Ophthalmic 眼科學 | TFDA-01830 | ISO | ISO 18369-4:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials | 原採認標準 |
| 587 | 10 Ophthalmic 眼科學 | TFDA-01831 | ISO | ISO 8980-1:2017 | 2017 | Ophthalmic optics - Uncut finished spectacle lenses - Part 1: Specifications for single-vision and multifocal lenses | 原採認標準 |
| 588 | 10 Ophthalmic 眼科學 | TFDA-01832 | ISO | ISO 8980-2:2017 | 2017 | Ophthalmic optics - Uncut finished spectacle lenses - Part 2: Specifications for power-variation lenses | 原採認標準 |

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| 589 | 10 Ophthalmic 眼科學 | TFDA-02043 | ISO | ISO 11979-7:2018 | 2018 | Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia | 109 年度新增採認標準 |
| 590 | 10 Ophthalmic 眼科學 | TFDA-02043 | ISO | ISO 11979-7:2018 | 2018 | Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia | 原採認標準 |
| 591 | 10 Ophthalmic 眼科學 | TFDA-02044 | ISO | ISO 11979-1:2018 | 2018 | Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary - Third Edition | 109 年度新增採認標準 |
| 592 | 10 Ophthalmic 眼科學 | TFDA-02045 | ASTM | ASTM D882-18 | 2018 | Standard Test Method for Tensile Properties of Thin Plastic Sheeting | 109 年度新增採認標準 |
| 593 | 11 Orthopaedics 骨科學 | TFDA-00082 | ISO | ISO 5838-2:1991 | 1991 | Implants for surgery -- Skeletal pins and wires -- Part 2: Steinmann skeletal pins -- Dimensions | 原採認標準 |
| 594 | 11 Orthopaedics 骨科學 | TFDA-00083 | ISO | ISO 5838-3:1993 | 1993 | Implants for surgery -- Skeletal pins and wires -- Part 3: Kirschner skeletal wires | 原採認標準 |
| 595 | 11 Orthopaedics 骨科學 | TFDA-00884 | ISO | ISO 7207-1:2007 | 2007 | Implants for surgery -- Components for partial and total knee joint prostheses -- Part 1: Classification, definitions and designation of dimensions | 原採認標準 |
| 596 | 11 Orthopaedics 骨科學 | TFDA-00885 | ISO | ISO 14243-1:2009 | 2009 | Implants for surgery -- Wear of total knee-joint prostheses -- Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test | 原採認標準 |
| 597 | 11 Orthopaedics 骨科學 | TFDA-00887 | ISO | ISO 14602:2010 | 2010 | Non-active surgical implants -- Implants for osteosynthesis -- Particular requirements | 原採認標準 |
| 598 | 11 Orthopaedics 骨科學 | TFDA-01363 | ISO | ISO 14630:2012 | 2012 | Non-active surgical implants -- General requirements | 原採認標準 |
| 599 | 11 Orthopaedics 骨科學 | TFDA-01364 | ISO | ISO 5833:2002 | 2002 | Implants for Surgery - Acrylic Resin Cements - Second Edition | 原採認標準 |

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| 600 | 11 Orthopaedics 骨科學 | TFDA-01365 | ISO | ISO 5838-1:2013 | 2013 | Implants for surgery -- Metallic skeletal pins and wires -- Part 1: General requirements | 原採認標準 |
| 601 | 11 Orthopaedics 骨科學 | TFDA-01369 | ASTM | ASTM F1820-13 | 2013 | Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices | 原採認標準 |
| 602 | 11 Orthopaedics 骨科學 | TFDA-01380 | ASTM | ASTM F2665-09/(R)2014 | 2014 | Standard Specification for Total Ankle Replacement Prosthesi | 原採認標準 |
| 603 | 11 Orthopaedics 骨科學 | TFDA-01382 | ASTM | ASTM F2996-13 | 2013 | Standard practice for finite element analysis (FEA) of non-modular metallic orthopaedic hip femoral stems. | 原採認標準 |
| 604 | 11 Orthopaedics 骨科學 | TFDA-01617 | ASTM | ASTM D2990-17 | 2017 | Standard Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics | 原採認標準 |
| 605 | 11 Orthopaedics 骨科學 | TFDA-01618 | ASTM | ASTM D790-17 | 2017 | Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials | 原採認標準 |
| 606 | 11 Orthopaedics 骨科學 | TFDA-01619 | ASTM | ASTM F116-12/(R)2016 | 2016 | Standard Specification for Medical Screwdriver Bits | 原採認標準 |
| 607 | 11 Orthopaedics 骨科學 | TFDA-01625 | ASTM | ASTM F2091-15 | 2015 | Standard Specification for Acetabular Prostheses | 原採認標準 |
| 608 | 11 Orthopaedics 骨科學 | TFDA-01626 | ASTM | ASTM F2180-17 | 2017 | Standard Specification for Metallic Implantable Strands and Cables | 原採認標準 |
| 609 | 11 Orthopaedics 骨科學 | TFDA-01630 | ASTM | ASTM F2582-14 | 2014 | Standard Test Method for Impingement of Acetabular Prostheses | 原採認標準 |
| 610 | 11 Orthopaedics 骨科學 | TFDA-01631 | ASTM | ASTM F2887-17 | 2017 | Standard Specification for Total Elbow Prostheses | 原採認標準 |

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| 611 | 11 Orthopaedics 骨科學 | TFDA-01632 | ASTM | ASTM F2979-14 | 2014 | Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses | 原採認標準 |
| 612 | 11 Orthopaedics 骨科學 | TFDA-01633 | ASTM | ASTM F3161-16 | 2016 | Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions | 原採認標準 |
| 613 | 11 Orthopaedics 骨科學 | TFDA-01634 | ASTM | ASTM F451-16 | 2016 | Standard Specification for Acrylic Bone Cement | 原採認標準 |
| 614 | 11 Orthopaedics 骨科學 | TFDA-01636 | ISO | ISO 14242-2:2016 | 2016 | Implants for surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement | 原採認標準 |
| 615 | 11 Orthopaedics 骨科學 | TFDA-01637 | ISO | ISO 14243-2:2016 | 2016 | Implants for surgery - Wear of total knee-joint prostheses - Part 2: Methods of measurement | 原採認標準 |
| 616 | 11 Orthopaedics 骨科學 | TFDA-01639 | ISO | ISO 21535:2009/Amd1:2016 | 2016 | Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants | 原採認標準 |
| 617 | 11 Orthopaedics 骨科學 | TFDA-01640 | ISO | ISO 21536:2007/Amd1:2014 | 2014 | Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants - Amendment 1 | 原採認標準 |
| 618 | 11 Orthopaedics 骨科學 | TFDA-01641 | ISO | ISO 7207-2/Amd1:2016 | 2016 | Implants for surgery - Components for partial and total knee joint prostheses - Part 2: Articulating surfaces made of metal, ceramic and plastics materials | 原採認標準 |
| 619 | 11 Orthopaedics 骨科學 | TFDA-01833 | ASTM | ASTM D732-17 | 2017 | Standard Test Method for Shear Strength of Plastics by Punch Tool | 原採認標準 |
| 620 | 11 Orthopaedics 骨科學 | TFDA-01836 | ASTM | ASTM F1541:2017 | 2017 | Standard Specification and Test Methods for External Skeletal Fixation Devices | 原採認標準 |

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| 621 | 11 Orthopaedics 骨科學 | TFDA-01838 | ASTM | ASTM F1829-17 | 2017 | Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear | 原採認標準 |
| 622 | 11 Orthopaedics 骨科學 | TFDA-01839 | ASTM | ASTM F1978:2018 | 2018 | Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser | 原採認標準 |
| 623 | 11 Orthopaedics 骨科學 | TFDA-01840 | ASTM | ASTM F2028-17 | 2017 | Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation | 原採認標準 |
| 624 | 11 Orthopaedics 骨科學 | TFDA-01842 | ASTM | ASTM F2502-:2017 | 2017 | Test Methods For Intervertebral Body Fusion Devices | 原採認標準 |
| 625 | 11 Orthopaedics 骨科學 | TFDA-01843 | ISO | ISO 13175-3:2012 | 2012 | Implants for surgery - Calcium phosphates - Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes | 原採認標準 |
| 626 | 11 Orthopaedics 骨科學 | TFDA-01908 | ASTM | ASTM F2267 - 04(2018) | 2018 | Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression | 原採認標準 |
| 627 | 11 Orthopaedics 骨科學 | TFDA-01909 | ASTM | ASTM F1714-96/(R)2018 | 2018 | Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices. | 原採認標準 |
| 628 | 11 Orthopaedics 骨科學 | TFDA-01910 | ASTM | ASTM F2423 - 11(2016) | 2016 | Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses. | 原採認標準 |
| 629 | 11 Orthopaedics 骨科學 | TFDA-01911 | ASTM | ASTM F2624 - 12(2016) | 2016 | Standard test method for static, dynamic, and wear assessment of extradiscal single level spinal constructs. | 原採認標準 |
| 630 | 11 Orthopaedics 骨科學 | TFDA-01912 | ASTM | ASTM F1378 - 18e1 | 2018 | Standard Specification for Shoulder Prostheses | 原採認標準 |
| 631 | 11 Orthopaedics 骨科學 | TFDA-01913 | ASTM | ASTM F1717 - 18 | 2018 | Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model | 原採認標準 |
| 632 | 11 Orthopaedics 骨科學 | TFDA-01914 | ASTM | ASTM F2077 - 18 | 2018 | Test Methods For Intervertebral Body Fusion Devices | 原採認標準 |

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| 633 | 11 Orthopaedics 骨科學 | TFDA-02046 | ASTM | ASTM F2554-18 | 2018 | Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems | 109 年度新增採認標準 |
| 634 | 11 Orthopaedics 骨科學 | TFDA-02047 | ISO | ISO 14242-3:2009 AMD1:2019 | 2019 | Implants for surgery — Wear of total hipjoint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test - First Edition | 109 年度新增採認標準 |
| 635 | 11 Orthopaedics 骨科學 | TFDA-02048 | ASTM | ASTM F2580-18 | 2018 | Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis | 109 年度新增採認標準 |
| 636 | 11 Orthopaedics 骨科學 | TFDA-02049 | ASTM | ASTM F2193 - 20 | 2020 | Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System | 109 年度新增採認標準 |
| 637 | 11 Orthopaedics 骨科學 | TFDA-02050 | ISO | ISO 14242-1:2014+A1:2018 | 2018 | Implants for surgery — Wear of total hipjoint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test | 109 年度新增採認標準 |
| 638 | 11 Orthopaedics 骨科學 | TFDA-02051 | ISO | ISO 19227:2018 | 2018 | Implants for surgery - Cleanliness of orthopedic implants - General requirements - First Edition | 109 年度新增採認標準 |
| 639 | 11 Orthopaedics 骨科學 | TFDA-02052 | ASTM | ASTM F2789 - 10(2020) | 2020 | Standard Guide for Mechanical and Functional Characterization of Nucleus Devices | 109 年度新增採認標準 |
| 640 | 11 Orthopaedics 骨科學 | TFDA-02053 | ASTM | ASTM F2009 - 20 | 2020 | Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses | 109 年度新增採認標準 |
| 641 | 11 Orthopaedics 骨科學 | TFDA-02054 | ASTM | ASTM F2381 - 19 | 2019 | Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy | 109 年度新增採認標準 |
| 642 | 11 Orthopaedics 骨科學 | TFDA-02055 | ASTM | ASTM F2943 - 14(2019) | 2019 | Standard Guide for Presentation of End User Labeling Information for Orthopedic Implants Used in Joint Arthroplasty. | 109 年度新增採認標準 |

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| 643 | 11 Orthopaedics 骨科學 | TFDA-02056 | ASTM | ASTM F1357 - 14(2019) | 2019 | Standard Specification for Articulating Total Wrist Implants | 109 年度新增採認標準 |
| 644 | 11 Orthopaedics 骨科學 | TFDA-02057 | ASTM | ASTM F1611 - 20 | 2020 | Standard Specification for Intramedullary Reamers | 109 年度新增採認標準 |
| 645 | 11 Orthopaedics 骨科學 | TFDA-02058 | ASTM | ASTM F2385 - 15(2019) | 2019 | Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs | 109 年度新增採認標準 |
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| 647 | 11 Orthopaedics 骨科學 | TFDA-02060 | ASTM | ASTM E399 - 20 | 2020 | Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness KIc of Metallic Materials | 109 年度新增採認標準 |
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| 649 | 12 Physical Medicine 物理醫學科學 | TFDA-00162 | ISO | ISO 7176-13:1989 | 1989 | Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces | 原採認標準 |
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| 652 | 12 Physical Medicine 物理醫學科學 | TFDA-00793 | CNS | CNS 15037-2 | 2006 | 雙臂操作步行輔具－要求及測試法－第 2 部：帶輪助行器 | 原採認標準 |

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| 654 | 12 Physical Medicine 物理醫學科學 | TFDA-00795 | CNS | CNS 15024-4 | 2006 | 單臂操作之步行輔具－要求與測試方法－第 4 部：三腳或多腳步行手杖 | 原採認標準 |
| 655 | 12 Physical Medicine 物理醫學科學 | TFDA-00796 | CNS | CNS 14103-1 | 2009 | 義肢學與矯具學－詞彙－第 1 部：外用義肢與外用矯具之一般術語 | 原採認標準 |
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| 664 | 12 Physical Medicine 物理醫學科學 | TFDA-00805 | CNS | CNS 15265-2 | 2009 | 義肢學與矯具學－義肢組件之分類與描述－第 2 部：下肢義肢組件之描述 | 原採認標準 |

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| 665 | 12 Physical Medicine 物理醫學科學 | TFDA-00806 | CNS | CNS 15265-3 | 2009 | 義肢學與矯具學－義肢組件之分類與描述－第 3 部：上肢義肢組件之描述 | 原採認標準 |
| 666 | 12 Physical Medicine 物理醫學科學 | TFDA-00807 | CNS | CNS 15266 | 2009 | 義肢學—髖關節結構之測試方法 | 原採認標準 |
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| 668 | 12 Physical Medicine 物理醫學科學 | TFDA-00809 | CNS | CNS 15269 | 2009 | 義肢學－下肢義肢結構測試－要求與測試方法 | 原採認標準 |
| 669 | 12 Physical Medicine 物理醫學科學 | TFDA-00810 | CNS | CNS 14964 | 2007 | 輪椅－應用指導綱要 | 原採認標準 |
| 670 | 12 Physical Medicine 物理醫學科學 | TFDA-00811 | CNS | CNS 14964-1 | 2017 | 輪椅－第 1 部：靜態穩定性之測定 | 原採認標準 |
| 671 | 12 Physical Medicine 物理醫學科學 | TFDA-00812 | CNS | CNS 14964-2 | 2007 | 輪椅－第 2 部：動態穩定性之測定 | 原採認標準 |
| 672 | 12 Physical Medicine 物理醫學科學 | TFDA-00814 | CNS | CNS 14964-4 | 2017 | 輪椅－第 4 部：電動輪椅及代步車之耗能－理論行駛距離之測定 | 原採認標準 |
| 673 | 12 Physical Medicine 物理醫學科學 | TFDA-00815 | CNS | CNS 14964-6 | 2005 | 輪椅－第 6 部：電動輪椅最大速度、加速度與減速度之測定 | 原採認標準 |
| 674 | 12 Physical Medicine 物理醫學科學 | TFDA-00816 | CNS | CNS 14964-7 | 2006 | 輪椅－第 7 部：座椅及輪子尺度之量測 | 原採認標準 |
| 675 | 12 Physical Medicine 物理醫學科學 | TFDA-00817 | CNS | CNS 14964-8 | 2018 | 輪椅－第 8 部：輪椅靜力、衝擊與疲勞強度測試方法與要求 | 原採認標準 |
| 676 | 12 Physical Medicine 物理醫學科學 | TFDA-00819 | CNS | CNS 14964-10 | 2017 | 輪椅－第 10 部：電動輪椅越障能力試驗 | 原採認標準 |

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| 677 | 12 Physical Medicine 物理醫學科學 | TFDA-00821 | CNS | CNS 14964-13 | 2006 | 輪椅－第 13 部：測試表面摩擦係數之測定 | 原採認標準 |
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| 679 | 12 Physical Medicine 物理醫學科學 | TFDA-00823 | CNS | CNS 14964-15 | 2007 | 輪椅－第 15 部：資訊宣告、文件與標示之要求 | 原採認標準 |
| 680 | 12 Physical Medicine 物理醫學科學 | TFDA-00825 | CNS | CNS 14964-19 | 2013 | 輪椅－第 19 部：機動車輛使用之輪型移動裝置 | 原採認標準 |
| 681 | 12 Physical Medicine 物理醫學科學 | TFDA-00826 | CNS | CNS 14964-21 | 2019 | 輪椅－第 21 部：電動輪椅及電動代步車之電磁相容性要求和測試方法 | 原採認標準 |
| 682 | 12 Physical Medicine 物理醫學科學 | TFDA-00827 | CNS | CNS 14964-22 | 2007 | 輪椅－第 22 部：設定程序 | 原採認標準 |
| 683 | 12 Physical Medicine 物理醫學科學 | TFDA-00935 | ISO | ISO 7176-4:2008 | 2008 | Wheelchairs -- Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range | 原採認標準 |
| 684 | 12 Physical Medicine 物理醫學科學 | TFDA-00936 | ISO | ISO 7176-5:2008 | 2008 | Wheelchairs -- Part 5: Determination of dimensions, mass and manoeuvring space | 原採認標準 |
| 685 | 12 Physical Medicine 物理醫學科學 | TFDA-00937 | ISO | ISO 7176-9:2009 | 2009 | Wheelchairs -- Part 9: Climatic tests for electric wheelchairs | 原採認標準 |
| 686 | 12 Physical Medicine 物理醫學科學 | TFDA-00938 | ISO | ISO 7176-10:2008 | 2008 | Wheelchairs -- Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs | 原採認標準 |
| 687 | 12 Physical Medicine 物理醫學科學 | TFDA-00939 | ISO | ISO 7176-14:2008 | 2008 | Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods | 原採認標準 |

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| 689 | 12 Physical Medicine 物理醫學科學 | TFDA-01383 | CNS | CNS 15469-1 | 2011 | 步行輔具杖端－要求與試驗方法－第 1 部：杖端摩擦力 (Tips for assistive products for walking - Requirements and test methods - Part 1: Friction of tips) (IDT: ISO 24415-1:2009) | 原採認標準 |
| 690 | 12 Physical Medicine 物理醫學科學 | TFDA-01384 | CNS | CNS 15469-2 | 2013 | 步行輔具杖端－要求與試驗方法－第 2 部：拐杖杖端耐用性 Tips for assistive products for walking − Requirements and test methods − Part 2: Durability of tips for crutches (IDT: ISO 24415-2:2011) | 原採認標準 |
| 691 | 12 Physical Medicine 物理醫學科學 | TFDA-01385 | ISO | ISO 7176-11:2012 | 2012 | Wheelchairs -- Part 11: Test dummies | 原採認標準 |
| 692 | 12 Physical Medicine 物理醫學科學 | TFDA-01386 | ISO | ISO 7176-16:2012 | 2012 | Wheelchairs -- Part 16: Resistance to ignition of postural support devices | 原採認標準 |
| 693 | 12 Physical Medicine 物理醫學科學 | TFDA-01387 | ISO | ISO 7176-3:2012 | 2012 | Wheelchairs -- Part 3: Determination of effectiveness of brakes | 原採認標準 |
| 694 | 12 Physical Medicine 物理醫學科學 | TFDA-01388 | CNS | CNS 15677-1 | 2013 | 失能者或生理障礙者之技術系統和輔具－ 輪椅束縛裝置和乘坐者安全拘束系統－ 第 1 部：全部系統之要求及測試方法 (Technical systems and aids for disabled or handicapped persons − Wheelchair tiedown and occupant-restraint systems − Part 1: Requirements and test methods for all systems) | 原採認標準 |
| 695 | 12 Physical Medicine 物理醫學科學 | TFDA-01642 | CNS | CNS 14964-16 | 2014 | 輪椅－第 16 部：姿勢支撐裝置之耐燃性(Wheelchairs − Part 16: Resistance to ignition of postural support devices) | 原採認標準 |
| 696 | 12 Physical Medicine 物理醫學科學 | TFDA-01643 | CNS | CNS 14964-25 | 2014 | 輪椅－第 25 部：電動輪椅之電池組及充電器(Wheelchairs − Part 25: Batteries and chargers for powered wheelchairs) | 原採認標準 |

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| 697 | 12 Physical Medicine 物理醫學科學 | TFDA-01645 | CNS | CNS 14964-3 | 2015 | 輪椅－第 3 部：煞車有效性之測定 | 原採認標準 |
| 698 | 12 Physical Medicine 物理醫學科學 | TFDA-01646 | CNS | CNS 14964-5 | 2017 | 輪椅－第 5 部：尺度、質量及操控空間之測定 | 原採認標準 |
| 699 | 12 Physical Medicine 物理醫學科學 | TFDA-01647 | CNS | CNS 14964-9 | 2014 | 輪椅－第 9 部：電動輪椅之耐候試驗(Wheelchairs − Part 9: Climatic tests for electric wheelchairs) | 原採認標準 |
| 700 | 12 Physical Medicine 物理醫學科學 | TFDA-01648 | CNS | CNS 15191 | 2012 | 木手杖 | 原採認標準 |
| 701 | 12 Physical Medicine 物理醫學科學 | TFDA-01649 | CNS | CNS 15192 | 2013 | 非木質手杖 | 原採認標準 |
| 702 | 12 Physical Medicine 物理醫學科學 | TFDA-01650 | CNS | CNS 15628-4 | 2015 | 輪椅乘坐系統－第 4 部：作為機動車輛之乘坐系統(Wheelchair seating − Part 4: Seating systems for use in motor vehicles) | 原採認標準 |
| 703 | 12 Physical Medicine 物理醫學科學 | TFDA-01652 | CNS | CNS 15910-1 | 2016 | 家用之褥瘡防止鋪墊－第 1 部：種類 | 原採認標準 |
| 704 | 12 Physical Medicine 物理醫學科學 | TFDA-01653 | CNS | CNS 15910-2 | 2016 | 家用之褥瘡防止鋪墊－第 2 部：替換靜態型 | 原採認標準 |
| 705 | 12 Physical Medicine 物理醫學科學 | TFDA-01654 | CNS | CNS 15910-3 | 2016 | 家用之褥瘡防止鋪墊－第 3 部：壓力交替型 | 原採認標準 |
| 706 | 12 Physical Medicine 物理醫學科學 | TFDA-01655 | EN | EN 12183:2014 | 2014 | Manual wheelchairs - Requirements and test methods | 原採認標準 |
| 707 | 12 Physical Medicine 物理醫學科學 | TFDA-01656 | EN | EN 12184:2014 | 2014 | Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods | 原採認標準 |
| 708 | 12 Physical Medicine 物理醫學科學 | TFDA-01659 | ISO | ISO 7176-1:2014 | 2014 | Wheelchairs - Part 1: Determination of Static Stability | 原採認標準 |

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| 709 | 12 Physical Medicine 物理醫學科學 | TFDA-01661 | ISO | ISO 7176-22:2014 | 2014 | Wheelchairs -- Part 22: Set-up procedures | 原採認標準 |
| 710 | 12 Physical Medicine 物理醫學科學 | TFDA-01662 | ISO | ISO 7176-8:2014 | 2014 | Wheelchairs -- Part 8: Requirements and test methods for static, impact and fatigue strengths | 原採認標準 |
| 711 | 12 Physical Medicine 物理醫學科學 | TFDA-01844 | CNS | CNS 16010-1 | 2017 | 尿液吸收輔具－詞彙－第 1 部：尿液失禁狀態 | 原採認標準 |
| 712 | 12 Physical Medicine 物理醫學科學 | TFDA-01845 | CNS | CNS 16010-2 | 2017 | 尿液吸收輔具－詞彙－第 2 部：產品 | 原採認標準 |
| 713 | 12 Physical Medicine 物理醫學科學 | TFDA-01846 | CNS | CNS 16010-3 | 2017 | 尿液吸收輔具－詞彙－第 3 部：產品型式識別 | 原採認標準 |
| 714 | 12 Physical Medicine 物理醫學科學 | TFDA-01847 | IEC | IEC 60601-2-3:2016 | 2016 | Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of shortwave therapy equipment | 原採認標準 |
| 715 | 12 Physical Medicine 物理醫學科學 | TFDA-01848 | IEC | IEC 60601-2-6:2016 | 2016 | Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment | 原採認標準 |
| 716 | 12 Physical Medicine 物理醫學科學 | TFDA-01849 | ISO | ISO 7176-19:2015+A1:2015 | 2015 | Wheelchairs Part 19: Wheeled mobility devices for use as seats in motor vehicles | 原採認標準 |
| 717 | 12 Physical Medicine 物理醫學科學 | TFDA-01850 | ISO | ISO 7176-2:2017 | 2017 | Wheelchairs - Part 2: Determination of Dynamic Stability of Electric Wheelchairs | 原採認標準 |
| 718 | 12 Physical Medicine 物理醫學科學 | TFDA-01851 | ISO | ISO 7176-6:2018 | 2018 | Wheelchairs - Part 6:Determination of maximum speed, acceleration and deceleration of electric wheelchairs | 原採認標準 |
| 719 | 12 Physical Medicine 物理醫學科學 | TFDA-01876 | ISO | ISO 7176-28:2012 | 2012 | Wheelchairs - Part 28: Requirements and test methods for stair-climbing devices | 原採認標準 |

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| 720 | 12 Physical Medicine 物理醫學科學 | TFDA-02061 | CNS | CNS 14964-28 | 2016 | 輪椅－第 28 部：爬梯裝置之要求與測試方法 1 | 109 年度新增採認標準 |
| 721 | 12 Physical Medicine 物理醫學科學 | TFDA-02061 | CNS | CNS 14964-28 | 2016 | 輪椅－第 28 部：爬梯裝置之要求與測試方法 | 原採認標準 |
| 722 | 12 Physical Medicine 物理醫學科學 | TFDA-02062 | ISO | ISO 11199-2:2005 | 2005 | Walking aids manipulated by both arms—Requirements and test methods—Part 2: Rollators | 109 年度新增採認標準 |
| 723 | 12 Physical Medicine 物理醫學科學 | TFDA-02063 | CNS | CNS 16051 | 2018 | 具電動輔助起站及坐下機構之座椅與椅座 | 109 年度新增採認標準 |
| 724 | 12 Physical Medicine 物理醫學科學 | TFDA-02064 | CNS | CNS 16077 | 2018 | 身心障礙者移位用起吊裝置－要求及試驗法 | 109 年度新增採認標準 |
| 725 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00345 | CLSI | AUTO4-A | 2001 | Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard | 原採認標準 |
| 726 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00489 | CLSI | AUTO2-A2 | 2006 | Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition | 原採認標準 |
| 727 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00490 | CLSI | AUTO5-A | 2001 | Laboratory Automation: Electromechanical Interfaces; Approved Standard | 原採認標準 |
| 728 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00491 | CLSI | AUTO7-A | 2004 | Laboratory Automation: Data Content for Specimen Identification; Approved Standard | 原採認標準 |

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| 729 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00588 | IEC | ISO/IEC 25062:2006 | 2006 | Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability test reports | 原採認標準 |
| 730 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00644 | CLSI | AUTO8-A | 2006 | Managing and Validating Laboratory Information Systems; Approved Guideline | 原採認標準 |
| 731 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00735 | CLSI | AUTO10-A | 2006 | Autoverification of Clinical Laboratory Test Results | 原採認標準 |
| 732 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00852 | CLSI | AUTO03-A2 | 2009 | Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard-Second Edition | 原採認標準 |
| 733 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00959 | IEC | IEC/TR 80002-1 ed1.0 :2009 | 2009 | Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software | 原採認標準 |
| 734 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00961 | CNS | CNS 14232-1 | 2010 | 健康資訊交換第七層協定－第 1 部：簡介 | 原採認標準 |
| 735 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00962 | CNS | CNS 14232-4 | 2010 | 健康資訊交換第七層協定－第 4 部：醫囑 | 原採認標準 |
| 736 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00963 | CNS | CNS 14232-5 | 2010 | 健康資訊交換第七層協定－第 5 部：查詢 | 原採認標準 |

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| 737 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00964 | CNS | CNS 14232-6 | 2010 | 健康資訊交換第七層協定－第 6 部：財務管理 | 原採認標準 |
| 738 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00965 | CNS | CNS 14232-7 | 2010 | 健康資訊交換第七層協定－第 7 部：觀察報告 | 原採認標準 |
| 739 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00966 | CNS | CNS 14232-8 | 2010 | 健康資訊交換第七層協定－第 8 部：公用主檔 | 原採認標準 |
| 740 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00967 | CNS | CNS 14232-9 | 2010 | 健康資訊交換第七層協定－第 9 部：醫療紀錄/資訊管理 | 原採認標準 |
| 741 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00968 | CNS | CNS 14232-10 | 2010 | 健康資訊交換第七層協定－第 10 部：排程 | 原採認標準 |
| 742 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00969 | CNS | CNS 14232-11 | 2010 | 健康資訊交換第七層協定－第 11 部：病患轉診 | 原採認標準 |
| 743 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00970 | CNS | CNS 14232-12 | 2010 | 健康資訊交換第七層協定－第 12 部：病患照護 | 原採認標準 |
| 744 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00971 | CNS | CNS 14232-13 | 2010 | 健康資訊交換第七層協定－第 13 部：臨床實驗室自動化 | 原採認標準 |

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| 746 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00973 | CNS | CNS 14232-15 | 2010 | 健康資訊交換第七層協定－第 15 部：人事管理 | 原採認標準 |
| 747 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01052 | AAMI | AAMI SW87:2012 | 2012 | Application of quality management system concepts to medical device data systems | 原採認標準 |
| 748 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01054 | AAMI | AAMI TIR80001-2-1:2012 | 2012 | Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples | 原採認標準 |
| 749 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01055 | AAMI | AAMI TIR80001-2-2:2012 | 2012 | Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls | 原採認標準 |
| 750 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01056 | AAMI | AAMI TIR80001-2-3:2012 | 2012 | Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks | 原採認標準 |
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| 752 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01059 | CNS | CNS 14232-16 | 2010 | 健康資訊交換第七層協定－第１６部：附錄 (Health Level Seven (HL7) - Part 16: Appendix) | 原採認標準 |

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| 753 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01060 | CNS | CNS 14232-2 | 2010 | 健康資訊交換第七層協定－第２部：控制 (Health Level Seven (HL7) - Part 2: Control) | 原採認標準 |
| 754 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01061 | CNS | CNS 14232-3 | 2010 | 健康資訊交換第七層協定－第３部：病患管理 (Health Level Seven (HL7) - Part 3: Patient administration) | 原採認標準 |
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| 761 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01070 | ISO | ISO/IEC 25001:2014 | 2014 | Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Planning and management - Second Edition | 原採認標準 |
| 762 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01071 | ISO | ISO/IEC 25051:2014 | 2014 | Software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing - Second Edition | 原採認標準 |
| 763 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01074 | ISO | ISO/IEEE 11073-10404:2010 | 2010 | Health informatics Personal health device communication Part 10404: Device specialization Pulse oximeter | 原採認標準 |
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| 765 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01076 | ISO | ISO/IEEE 11073-10407:2010 | 2010 | ISO/IEEE Health informatics Personal health device communication Part 10407: Device specialization Blood pressure monitor | 原採認標準 |
| 766 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01077 | ISO | ISO/IEEE 11073-10408:2010 | 2010 | Health Informatics-Personal Health Device Communication Part 10408: Device Specialization-Thermometer | 原採認標準 |
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| 771 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01665 | IEC | IEC 82304-1:2016 | 2016 | Health software - Part 1: General requirements for product safety - Edition 1.0 | 原採認標準 |
| 772 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01666 | IEC | IEC/TR 80001-2-5:2014 | 2014 | Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems - Edition 1.0 | 原採認標準 |
| 773 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01667 | IEC | IEC/TR 80002-3:2014 | 2014 | Medical device software –Part 3: Process reference model of medical device software life cycle processes (IEC 62304) | 原採認標準 |
| 774 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01668 | IEEE | IEEE Std 11073-10417-2015 | 2015 | Health Informatics-Personal health device communication Part 10417: Device specialization-Glucose meter | 原採認標準 |
| 775 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01669 | IEEE | IEEE Std 11073-10422-2016 | 2016 | Health informatics-Personal health device communication Part 10422: Device specialization - Urine analyzer | 原採認標準 |
| 776 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01670 | IEEE | IEEE Std 11073-10424-2014 | 2014 | Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE) | 原採認標準 |

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| 784 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01855 | IEEE | IEEE 11073-20601:2016 | 2016 | Health informatics--Personal health device communication Part 20601: Application profile-Optimized Exchange Protocol. | 原採認標準 |

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| 785 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01856 | IEEE | IEEE/IEC/ISO 12207:2017 | 2017 | Systems and software engineering -- Software life cycle processes | 原採認標準 |
| 786 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01857 | ISO | ISO/IEEE 11073-10102:2014 | 2014 | Health informatics -- Point-of-care medical device communication Part 10102: Nomenclature --Annotated ECG | 原採認標準 |
| 787 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01858 | ISO | ISO/IEEE 11073-10417:2017 | 2017 | IEEE Health informatics -- Personal health device communication Part 10417: Device Specialization -- Glucose Meter | 原採認標準 |
| 788 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01915 | AAMI | AAMI TIR45:2012/(R)2018 | 2018 | Guidance on the use of AGILE practices in the development of medical device software | 原採認標準 |
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| 790 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01917 | ISO | ISO/IEEE 11073-10418:2014/COR 1:2016 | 2016 | Health informatics—Personal health device communication—Part 10418 Device specialization—International normalized ratio (INR) monitor | 原採認標準 |
| 791 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01918 | IEEE | IEEE Std 11073-10424-2014/Cor 1-2017 | 2017 | Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE) | 原採認標準 |
| 792 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-02065 | ISO | ISO/IEEE 11073-10101+A11:2017 | 2017 | ISO/IEEE Health Informatics - Point-Of-Care Medical Device Communication - Part 10101: Nomenclature | 109 年度新增採認標準 |

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| 799 | 14 Radiology 放射學科學 | TFDA-00412 | IEC | IEC 61847: 1998 | 1998 | Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics Ed. 1.0 | 原採認標準 |
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| 802 | 14 Radiology 放射學科學 | TFDA-00417 | ISO | ISO 9236-1:2004 | 2004 | Photography - Sensitometry of screen/film systems for medical radiography - Part 1: Determination of sensitometric curve shape, speed and average gradient | 原採認標準 |
| 803 | 14 Radiology 放射學科學 | TFDA-00418 | ISO | ISO 4090:2001 | 2001 | Photography - Medical radiographic cassette/screens/films and hard-copy imaging films - Dimensions and specifications | 原採認標準 |
| 804 | 14 Radiology 放射學科學 | TFDA-00419 | ISO | ISO 5799:1991 | 1991 | Photography -- Direct-exposing medical and dental radiographic film/process systems -- Determination of ISO speed and ISO average gradient | 原採認標準 |
| 805 | 14 Radiology 放射學科學 | TFDA-00421 | ISO | ISO 15367-1:2003 | 2003 | Lasers and laser-related equipment -- Test methods for determination of the shape of a laser beam wavefront -- Part 1: Terminology and fundamental aspects | 原採認標準 |
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| 807 | 14 Radiology 放射學科學 | TFDA-00431 | IEC | IEC/TR 60825-14 - Ed. 1.0 | 2004 | Safety of laser products - Part 14: A user's guide | 原採認標準 |
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| 811 | 14 Radiology 放射學科學 | TFDA-00747 | CNS | CNS 15211 | 2010 | 健康資訊學－醫學數位影像及通信暨工作流程及資料處理 | 原採認標準 |
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| 814 | 14 Radiology 放射學科學 | TFDA-00974 | IEC | IEC 60976:2007 ed2.0 | 2007 | Medical electrical equipment - Medical electron accelerators - Functional performance characteristics | 原採認標準 |
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| 816 | 14 Radiology 放射學科學 | TFDA-01247 | ISO | ISO TR 21254-4:2011 | 2011 | Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Part 4: Inspection, detection and measurement - First Edition | 原採認標準 |
| 817 | 14 Radiology 放射學科學 | TFDA-01390 | CNS | CNS 15584 | 2013 | X 射線管組件之永久過濾測定 (Determination of the permanent filtration of X-ray tube assemblies (IDT: IEC 60522:1999)) | 原採認標準 |
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| 821 | 14 Radiology<br>放射學科學 | TFDA-01395 | IEC | IEC 60601-2-11:2013 | 2013 | Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment - Edition 3.0 | 原採認標準 |
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| 832 | 14 Radiology<br>放射學科學 | TFDA-01417 | IEC | IEC 61331-3:2014 | 2004 | Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields - Edition 2.0 | 原採認標準 |
| 833 | 14 Radiology<br>放射學科學 | TFDA-01418 | IEC | IEC 61674:2012 | 2012 | Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging - Edition 2.0 | 原採認標準 |
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| 835 | 14 Radiology<br>放射學科學 | TFDA-01420 | IEC | IEC 62083:2009 | 2009 | Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems | 原採認標準 |
| 836 | 14 Radiology<br>放射學科學 | TFDA-01421 | IEC | IEC 62127-1 ed1.1 Consol. with am1 | 2013 | Ultrasonics—Hydrophones—Part 1: Measurement and characterization of medical ultrasonic fields up to 40 megahertz (MHz). | 原採認標準 |
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| 839 | 14 Radiology 放射學科學 | TFDA-01426 | IEEE | IEEE N42.13, 2004 | 2004 | Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides | 原採認標準 |
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| 841 | 14 Radiology 放射學科學 | TFDA-01428 | ISO | ISO 21254-1:2011 | 2011 | Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 1: Definitions and general principles | 原採認標準 |
| 842 | 14 Radiology 放射學科學 | TFDA-01429 | ISO | ISO 21254-2:2011 | 2011 | Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 2: Threshold determination | 原採認標準 |
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| 844 | 14 Radiology 放射學科學 | TFDA-01431 | ISO | ISO/ASTM 51275:2013 | 2013 | Practice for use of a radiochromic film dosimetry system | 原採認標準 |
| 845 | 14 Radiology 放射學科學 | TFDA-01432 | ISO | ISO/ASTM 51607:2013 | 2013 | Practice for use of an alanine-EPR dosimetry system | 原採認標準 |
| 846 | 14 Radiology 放射學科學 | TFDA-01681 | ASTM | ASTM F2978-13 | 2013 | Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging | 原採認標準 |
| 847 | 14 Radiology 放射學科學 | TFDA-01701 | EN | EN 62220-1-1:2015 | 2015 | Medical electrical equipment - Characteristics of digital x-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging | 原採認標準 |

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| 848 | 14 Radiology<br>放射學科學 | TFDA-01702 | EN | EN 62570:2015 | 2015 | Standard practice for marking medical devices and other items for safety in the magnetic resonance environment | 原採認標準 |
| 849 | 14 Radiology<br>放射學科學 | TFDA-01703 | IEC | IEC 60601-2-1:2014 | 2014 | Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV | 原採認標準 |
| 850 | 14 Radiology<br>放射學科學 | TFDA-01704 | IEC | IEC 60601-2-17:2015 | 2015 | Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment | 原採認標準 |
| 851 | 14 Radiology<br>放射學科學 | TFDA-01706 | IEC | IEC 60601-2-33:2015 | 2015 | Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis - Edition 3.2 Consolidated Reprint | 原採認標準 |
| 852 | 14 Radiology<br>放射學科學 | TFDA-01707 | IEC | IEC 60601-2-36:2015 | 2015 | Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy | 原採認標準 |
| 853 | 14 Radiology<br>放射學科學 | TFDA-01708 | IEC | IEC 60601-2-37:2015 | 2015 | Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment - Edition 2.1; Consolidated Reprint | 原採認標準 |
| 854 | 14 Radiology<br>放射學科學 | TFDA-01709 | IEC | IEC 60601-2-44+A2 :2016 | 2016 | Medical electrical equipment Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography - AMD: March 31, 2012; AMD: June 30, 2013; AMD: July 31, 2016 | 原採認標準 |

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| 855 | 14 Radiology<br>放射學科學 | TFDA-01710 | IEC | IEC 60601-2-45:2015 | 2015 | Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices - Edition 3.1; Consolidated Reprint | 原採認標準 |
| 856 | 14 Radiology<br>放射學科學 | TFDA-01712 | IEC | IEC 60601-2-62:2013 | 2013 | Medical electrical equipment—Part 2–62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment | 原採認標準 |
| 857 | 14 Radiology<br>放射學科學 | TFDA-01713 | IEC | IEC 60601-2-64:2015 | 2015 | Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment | 原採認標準 |
| 858 | 14 Radiology<br>放射學科學 | TFDA-01714 | IEC | IEC 60601-2-68:2015 | 2015 | Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-raybased image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment | 原採認標準 |
| 859 | 14 Radiology<br>放射學科學 | TFDA-01715 | IEC | IEC 60601-2-8:2015 | 2015 | Medical electrical equipment – Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV - Edition 2.1; Consolidated Reprint | 原採認標準 |
| 860 | 14 Radiology<br>放射學科學 | TFDA-01716 | IEC | IEC 60731:2011+A1:2016 | 2016 | Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy - Edition 3.1; Consolidated Reprint | 原採認標準 |
| 861 | 14 Radiology<br>放射學科學 | TFDA-01718 | ISO | ISO 11810:2016 | 2016 | Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Primary ignition, penetration, lame spread and secondary ignition | 原採認標準 |
| 862 | 14 Radiology<br>放射學科學 | TFDA-01720 | ISO | ISO/ASTM 51707-15 | 2015 | Guide for estimating uncertainties in dosimetry for radiation processing | 原採認標準 |

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| 864 | 14 Radiology<br>放射學科學 | TFDA-01861 | IEC | IEC 60601-2-63:2017 | 2017 | Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment | 原採認標準 |
| 865 | 14 Radiology<br>放射學科學 | TFDA-01862 | IEC | IEC 60601-2-65:2017 | 2017 | Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment | 原採認標準 |
| 866 | 14 Radiology<br>放射學科學 | TFDA-01863 | ISO | ISO 11554:2017 | 2017 | Optics and photonics -- Lasers and laser-related equipment -- Test methods for laser beam power, energy and temporal characteristics | 原採認標準 |
| 867 | 14 Radiology<br>放射學科學 | TFDA-01864 | ISO | ISO 12052:2017 | 2017 | Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management | 原採認標準 |
| 868 | 14 Radiology<br>放射學科學 | TFDA-01919 | IEC | IEC 60601-2-54:2009 +AMD1:2015+AMD 2:2018 CSV | 2018 | Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy | 原採認標準 |
| 869 | 14 Radiology<br>放射學科學 | TFDA-01920 | ISO | ISO 11670:2003 /COR 1:2004 | 2004 | Lasers and laser-related equipment - Test methods for laser beam parameters - Beam positional stability | 原採認標準 |
| 870 | 14 Radiology<br>放射學科學 | TFDA-01921 | ASTM | ASTM D7866-14a | 2014 | Standard Specification for Radiation Attenuating Protective Gloves | 原採認標準 |
| 871 | 14 Radiology<br>放射學科學 | TFDA-02070 | IEC | EC 61223-3-5:2019 | 2019 | Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment | 109 年度新增採認標準 |

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| 872 | 14 Radiology 放射學科學 | TFDA-02071 | IEC | IEC 80601-2-26:2019 | 2019 | Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph | 109 年度新增採認標準 |
| 873 | 14 Radiology 放射學科學 | TFDA-02072 | ISO | ISO 11990:2018 | 2018 | Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes Part 2: Tracheal tube cuffs | 109 年度新增採認標準 |
| 874 | 14 Radiology 放射學科學 | TFDA-02073 | ISO | ISO 11551:2019 | 2019 | Optics and optical instruments - Lasers and laser-related equipment - Test method for absorptance of optical laser components | 109 年度新增採認標準 |
| 875 | 14 Radiology 放射學科學 | TFDA-02074 | NEMA | DICOM PS3.1 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview | 109 年度新增採認標準 |
| 876 | 14 Radiology 放射學科學 | TFDA-02075 | NEMA | DICOM PS3.10 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for Media Interchange | 109 年度新增採認標準 |
| 877 | 14 Radiology 放射學科學 | TFDA-02076 | NEMA | DICOM PS3.11 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles | 109 年度新增採認標準 |
| 878 | 14 Radiology 放射學科學 | TFDA-02077 | NEMA | DICOM PS3.12 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange | 109 年度新增採認標準 |
| 879 | 14 Radiology 放射學科學 | TFDA-02078 | NEMA | DICOM PS3.14 2020bc | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function | 109 年度新增採認標準 |
| 880 | 14 Radiology 放射學科學 | TFDA-02079 | NEMA | DICOM PS3.15 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 15: Security and System Management Profiles | 109 年度新增採認標準 |
| 881 | 14 Radiology 放射學科學 | TFDA-02080 | NEMA | DICOM PS3.16 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource | 109 年度新增採認標準 |
| 882 | 14 Radiology 放射學科學 | TFDA-02081 | NEMA | DICOM PS3.17 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 17: Explanatory Information | 109 年度新增採認標準 |
| 883 | 14 Radiology 放射學科學 | TFDA-02082 | NEMA | DICOM PS3.18 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Access to DICOM Persistent Objects (WADO) | 109 年度新增採認標準 |

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| 884 | 14 Radiology 放射學科學 | TFDA-02083 | NEMA | DICOM PS3.19 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 19: Application Hosting | 109 年度新增採認標準 |
| 885 | 14 Radiology 放射學科學 | TFDA-02084 | NEMA | DICOM PS3.2 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 2: Conformance | 109 年度新增採認標準 |
| 886 | 14 Radiology 放射學科學 | TFDA-02085 | NEMA | DICOM PS3.20 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 20: Transformation of DICOM to and from HL7 Standards | 109 年度新增採認標準 |
| 887 | 14 Radiology 放射學科學 | TFDA-02086 | NEMA | DICOM PS3.3 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions | 109 年度新增採認標準 |
| 888 | 14 Radiology 放射學科學 | TFDA-02087 | NEMA | DICOM PS3.4 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications | 109 年度新增採認標準 |
| 889 | 14 Radiology 放射學科學 | TFDA-02088 | NEMA | DICOM PS3.5 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding | 109 年度新增採認標準 |
| 890 | 14 Radiology 放射學科學 | TFDA-02089 | NEMA | DICOM PS3.6 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 6: Data Dictionary | 109 年度新增採認標準 |
| 891 | 14 Radiology 放射學科學 | TFDA-02090 | NEMA | DICOM PS3.7 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 7: Message Exchange | 109 年度新增採認標準 |
| 892 | 14 Radiology 放射學科學 | TFDA-02091 | NEMA | DICOM PS3.8 2020c | 2020 | Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange | 109 年度新增採認標準 |
| 893 | 14 Radiology 放射學科學 | TFDA-02092 | IEC | IEC 60601-2-43:2010 +AMD1:2017+AMD 2:2019 CSV | 2019 | Medical electrical equipment - Part 2-43:Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures | 109 年度新增採認標準 |
| 894 | 15 Sterility 滅菌 | TFDA-00034 | ISO | ISO 14644-4:2001 | 2001 | Cleanrooms and Associated Controlled Environments - Part 4: Design, Construction and Start-up | 原採認標準 |

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| 895 | 15 Sterility 滅菌 | TFDA-00035 | ISO | ISO 14698-1:2003 | 2003 | Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods | 原採認標準 |
| 896 | 15 Sterility 滅菌 | TFDA-00036 | ISO | ISO 14698-2:2003 | 2003 | Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 2: Evaluation and Interpretation of Biocontamination Data | 原採認標準 |
| 897 | 15 Sterility 滅菌 | TFDA-00351 | ISO | ISO 13408-4:2005 | 2005 | Aseptic processing of health care products —Part 4: Clean-in-place technologies | 原採認標準 |
| 898 | 15 Sterility 滅菌 | TFDA-00354 | ISO | ISO 14644-5:2004 | 2004 | Cleanrooms and associated controlled environments —Part 5: Operations | 原採認標準 |
| 899 | 15 Sterility 滅菌 | TFDA-00355 | ISO | ISO 14644-7:2004 | 2004 | Cleanrooms and associated controlled environments —Part 7: Separative devices (clean air hoods, gloveboxes, isolators and minienvironments) | 原採認標準 |
| 900 | 15 Sterility 滅菌 | TFDA-00524 | ISO | ISO 11140-3:2007 | 2007 | Sterilization of health care products -- Chemical indicators -- Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test | 原採認標準 |
| 901 | 15 Sterility 滅菌 | TFDA-00525 | ISO | ISO 11140-4:2007 | 2007 | Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration | 原採認標準 |
| 902 | 15 Sterility 滅菌 | TFDA-00526 | ISO | ISO 11140-5:2007 | 2007 | Sterilization of health care products -- Chemical indicators -- Part 5: Class 2 indicators for Bowie and Dick-type air removal tests | 原採認標準 |
| 903 | 15 Sterility 滅菌 | TFDA-00529 | ISO | ISO 13408-3:2006 | 2006 | Aseptic processing of health care products -- Part 3: Lyophilization | 原採認標準 |
| 904 | 15 Sterility 滅菌 | TFDA-00530 | ISO | ISO 13408-5:2006 | 2006 | Aseptic processing of health care products -- Part 5: Sterilization in place | 原採認標準 |
| 905 | 15 Sterility 滅菌 | TFDA-00676 | CEN | EN 556-1:2001/AC:2006 | 2006 | Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices | 原採認標準 |

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| 906 | 15 Sterility 滅菌 | TFDA-00677 | ISO | ISO 17665-1:2006 | 2006 | Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices | 原採認標準 |
| 907 | 15 Sterility 滅菌 | TFDA-00865 | ISO | ISO 14937:2009 | 2009 | Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices | 原採認標準 |
| 908 | 15 Sterility 滅菌 | TFDA-00870 | ISO | ISO 15882:2008 | 2008 | Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results | 原採認標準 |
| 909 | 15 Sterility 滅菌 | TFDA-00947 | ISO | ISO/TS 17665-2:2009 | 2009 | Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1 | 原採認標準 |
| 910 | 15 Sterility 滅菌 | TFDA-01030 | AOAC | 6.2.02:2006 | 2006 | Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method | 原採認標準 |
| 911 | 15 Sterility 滅菌 | TFDA-01031 | AOAC | 6.2.03:2006 | 2006 | Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method | 原採認標準 |
| 912 | 15 Sterility 滅菌 | TFDA-01032 | AOAC | 6.2.05:2006 | 2006 | Testing Disinfectants Against Pseudomonas aeruginosa,Hard Surface Carrier Test Method. | 原採認標準 |
| 913 | 15 Sterility 滅菌 | TFDA-01033 | AOAC | 6.3.02:2006 | 2006 | Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes. | 原採認標準 |
| 914 | 15 Sterility 滅菌 | TFDA-01034 | AOAC | 6.3.05:2012 | 2012 | Sporicidal Activity of Disinfectants Method I. | 原採認標準 |
| 915 | 15 Sterility 滅菌 | TFDA-01035 | AOAC | 6.3.06:2012 | 2012 | Tuberculocidal Activity of Disinfectants. | 原採認標準 |
| 916 | 15 Sterility 滅菌 | TFDA-01036 | CNS | CNS 15449-2 | 2011 | 量測、控制及實驗室使用電氣設備安全規定－第 2 部：處理醫用材料及實驗室程序使用蒸汽之高壓滅菌鍋特殊規定 (Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes) | 原採認標準 |

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| 917 | 15 Sterility 滅菌 | TFDA-01037 | CNS | CNS 15690 | 2013 | 健康照護產品滅菌－用語 (Sterilization of health care products − Vocabulary) | 原採認標準 |
| 918 | 15 Sterility 滅菌 | TFDA-01038 | CNS | CNS 15691-1 | 2013 | 健康照護產品之無菌操作－第 1 部：一般要求 Aseptic processing of health care products − Part 1: General requirements (IDE ISO 13408-1:2006) | 原採認標準 |
| 919 | 15 Sterility 滅菌 | TFDA-01039 | CNS | CNS 15691-2 | 2013 | 健康照護產品之無菌操作－第 2 部：過濾 Aseptic processing of health care products − Part 2: Filtration (IDE ISO 13408-2:2006) | 原採認標準 |
| 920 | 15 Sterility 滅菌 | TFDA-01040 | CNS | CNS 15691-3 | 2013 | 健康照護產品之無菌操作－第 3 部：冷凍乾燥無菌操作 Aseptic processing of health care products − Part 3: Lyophilization (IDE ISO 13408-3:2006) | 原採認標準 |
| 921 | 15 Sterility 滅菌 | TFDA-01041 | CNS | CNS 15691-4 | 2013 | 健康照護產品之無菌操作－第 4 部：原地清潔 Aseptic processing of health care products − Part 4: Clean-in-place technologies (IDE ISO 13408-4:2005) | 原採認標準 |
| 922 | 15 Sterility 滅菌 | TFDA-01042 | CNS | CNS 15691-5 | 2013 | 健康照護產品之無菌操作－第 5 部：原地滅菌 Aseptic processing of health care products − Part 5: Sterilization in place (IDE ISO 13408-5:2006) | 原採認標準 |
| 923 | 15 Sterility 滅菌 | TFDA-01043 | CNS | CNS 15691-6 | 2013 | 健康照護產品之無菌操作－第 6 部：隔離裝置系統 Aseptic processing of health care products − Part 6: Isolator systems (IDE ISO 13408-6:2005) | 原採認標準 |
| 924 | 15 Sterility 滅菌 | TFDA-01047 | ISO | ISO 13408-6:2005/Amd 1:2013 | 2013 | Aseptic processing of health care products -- Part 6: Isolator systems | 原採認標準 |

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| 925 | 15 Sterility 滅菌 | TFDA-01048 | ISO | ISO 14160:2011 | 2011 | Sterilization of health care products -- Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization | 原採認標準 |
| 926 | 15 Sterility 滅菌 | TFDA-01049 | ISO | ISO 14644-8:2013 | 2013 | Cleanrooms and associated controlled environments -- Part 8: Classification of air cleanliness by chemical concentration (ACC) | 原採認標準 |
| 927 | 15 Sterility 滅菌 | TFDA-01051 | ISO | ISO/ASTM 52701:2013 | 2013 | Guide for performance characterization of dosimeters and dosimetry systems for use in radiation processing | 原採認標準 |
| 928 | 15 Sterility 滅菌 | TFDA-01721 | AAMI | AAMI TIR35:2016 | 2016 | Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits | 原採認標準 |
| 929 | 15 Sterility 滅菌 | TFDA-01722 | CNS | CNS 14622-1 | 2014 | 健康照護產品滅菌－生物指示劑－第 1 部：一般(Sterilization of health care products − Biological indicators − Part 1: General requirements) | 原採認標準 |
| 930 | 15 Sterility 滅菌 | TFDA-01723 | CNS | CNS 14622-2 | 2014 | 健康照護產品滅菌－生物指示劑－第 2 部：環氧乙烷滅菌程序之生物指示劑(Sterilization of health care products − Biological indicators − Part 2: Biological indicators for ethylene oxide sterilization processes) | 原採認標準 |
| 931 | 15 Sterility 滅菌 | TFDA-01724 | CNS | CNS 14622-3 | 2014 | 健康照護產品滅菌－生物指示劑－第 3 部：濕熱滅菌程序之生物指示劑(Sterilization of health care products − Biological indicators − Part 3: Biological indicators for moist heat sterilization processes) | 原採認標準 |
| 932 | 15 Sterility 滅菌 | TFDA-01725 | CNS | CNS 14622-4 | 2014 | 健康照護產品滅菌－生物指示劑－第 4 部：乾熱滅菌程序之生物指示劑(Sterilization of health care products − Biological indicators − Part 4: Biological indicators for dry heat sterilization processes) | 原採認標準 |

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| 933 | 15 Sterility 滅菌 | TFDA-01726 | CNS | CNS 14622-5 | 2014 | 健康照護產品滅菌－生物指示劑－第 5 部：低溫蒸汽及甲醛滅菌程序之生物指示劑(Sterilization of health care products − Biological indicators − Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes) | 原採認標準 |
| 934 | 15 Sterility 滅菌 | TFDA-01727 | CNS | CNS 15758-1 | 2014 | 最終滅菌醫療器材之包裝－第 1 部：材料、無菌屏障系統及包裝系統之要求(Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems) | 原採認標準 |
| 935 | 15 Sterility 滅菌 | TFDA-01728 | EN | EN 14180:2014 | 2014 | Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing | 原採認標準 |
| 936 | 15 Sterility 滅菌 | TFDA-01729 | EN | EN 1422:2014 | 2014 | Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods | 原採認標準 |
| 937 | 15 Sterility 滅菌 | TFDA-01730 | EN | EN 16615:2015 | 2015 | Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2) | 原採認標準 |
| 938 | 15 Sterility 滅菌 | TFDA-01731 | EN | EN 556-2:2015 | 2015 | Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” Part 2: Requirements for aseptically processed medical devices | 原採認標準 |
| 939 | 15 Sterility 滅菌 | TFDA-01733 | ISO | ISO 11138-1:2017 | 2017 | Sterilization of health care products — Biological indicators Part 1: General requirements | 原採認標準 |
| 940 | 15 Sterility 滅菌 | TFDA-01734 | ISO | ISO 11138-2:2017 | 2017 | Sterilization of health care products — Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes | 原採認標準 |
| 941 | 15 Sterility 滅菌 | TFDA-01735 | ISO | ISO 11138-3:2017 | 2017 | Sterilization of health care products - Biological indicators Part 3: Biological indicators for moist heat sterilization processes | 原採認標準 |

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| 942 | 15 Sterility 滅菌 | TFDA-01736 | ISO | ISO 11138-4:2017 | 2017 | Sterilization of health care products - Biological indicators Part 4: Biological indicators for dry heat sterilization processes | 原採認標準 |
| 943 | 15 Sterility 滅菌 | TFDA-01737 | ISO | ISO 11138-5:2017 | 2017 | Sterilization of health care products — Biological indicators Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes | 原採認標準 |
| 944 | 15 Sterility 滅菌 | TFDA-01738 | ISO | ISO 11140-1:2014 | 2014 | Sterilization of health care products -- Chemical indicators -- Part 1: General requirements | 原採認標準 |
| 945 | 15 Sterility 滅菌 | TFDA-01741 | ISO | ISO 13408-7:2012 | 2012 | Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products - CORR: August 31, 2015 | 原採認標準 |
| 946 | 15 Sterility 滅菌 | TFDA-01742 | ISO | ISO 14644-1:2015 | 2015 | Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration - Second Edition | 原採認標準 |
| 947 | 15 Sterility 滅菌 | TFDA-01743 | ISO | ISO 14644-2:2015 | 2015 | Cleanrooms and Associated Controlled Environments - Part 2: Specification for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1 | 原採認標準 |
| 948 | 15 Sterility 滅菌 | TFDA-01744 | ISO | ISO 20857:2010 | 2010 | Sterilization of health care products_- Dry heat_- Requirements for the development, validation and routine control of a sterilization process for medical devices | 原採認標準 |
| 949 | 15 Sterility 滅菌 | TFDA-01745 | ISO | ISO TIR16775:2014 | 2014 | Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 | 原採認標準 |
| 950 | 15 Sterility 滅菌 | TFDA-01761 | ISO | ISO 11137-2:2015 | 2015 | Sterilization of health care products - Radiation Part 2: Establishing the sterilization dose | 原採認標準 |
| 951 | 15 Sterility 滅菌 | TFDA-01762 | ISO | ISO 13408-1:2015 | 2015 | Aseptic processing of health care products Part 1: General requirements | 原採認標準 |
| 952 | 15 Sterility 滅菌 | TFDA-01865 | AAMI | AAMI ST55:2016 | 2016 | Table-Top Steam Sterilizers | 原採認標準 |

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| 953 | 15 Sterility 滅菌 | TFDA-01866 | ISO | ISO 11737-1:2018 | 2018 | Sterilization of medical devices -- Microbiological methods -- Part 1:Determination of a population of microorganisms on products | 原採認標準 |
| 954 | 15 Sterility 滅菌 | TFDA-01867 | ISO | ISO 13408-2:2018 | 2018 | Aseptic Processing of Health Care Products - Part 2: Filtration | 原採認標準 |
| 955 | 15 Sterility 滅菌 | TFDA-01922 | AAMI | AAMI ST50:2004/(R)2018 | 2018 | Dry heat (heated air) sterilizers | 原採認標準 |
| 956 | 15 Sterility 滅菌 | TFDA-01923 | AAMI | AAMI ST8 : 2013(R2018) | 2018 | Hospital steam sterilizers | 原採認標準 |
| 957 | 15 Sterility 滅菌 | TFDA-01924 | AAMI | AAMI ST24:1999/(R)2018 | 2018 | Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities | 原採認標準 |
| 958 | 15 Sterility 滅菌 | TFDA-01925 | AAMI | AAMI ST77:2013/(R)2018 | 2018 | Containment devices for reusable medical device sterilization, 2nd ed. | 原採認標準 |
| 959 | 15 Sterility 滅菌 | TFDA-02093 | ISO | ISO 18472:2018 | 2018 | Sterilization of health care products —Biological and chemical indicators —Test equipment | 109 年度新增採認標準 |
| 960 | 15 Sterility 滅菌 | TFDA-02094 | ISO | ISO 11138-7:2019 | 2019 | Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results | 109 年度新增採認標準 |
| 961 | 15 Sterility 滅菌 | TFDA-02095 | ASTM | ASTM F2315-18 | 2018 | Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels | 109 年度新增採認標準 |
| 962 | 15 Sterility 滅菌 | TFDA-02096 | ASTM | ASTM F2450-18 | 2018 | Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products | 109 年度新增採認標準 |
| 963 | 15 Sterility 滅菌 | TFDA-02097 | ISO | ISO 11135:2014+A1:2018 | 2018 | Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices | 109 年度新增採認標準 |
| 964 | 15 Sterility 滅菌 | TFDA-02098 | ISO | ISO 11607-1:2019 | 2019 | Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems | 109 年度新增採認標準 |

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| 965 | 15 Sterility 滅菌 | TFDA-02099 | ISO | ISO 11607-2:2019 | 2019 | Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes | 109 年度新增採認標準 |
| 966 | 15 Sterility 滅菌 | TFDA-02100 | ISO | ISO 11137-1:2015+A2:2018 | 2018 | Sterilization of health care products - Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices | 109 年度新增採認標準 |
| 967 | 15 Sterility 滅菌 | TFDA-02101 | ISO | ISO 14644-3:2019 | 2019 | Cleanrooms and associated controlled environments —Part 3: Test methods | 109 年度新增採認標準 |
| 968 | 15 Sterility 滅菌 | TFDA-02102 | ISO | ISO 11737-2:2019 | 2019 | Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process | 109 年度新增採認標準 |
| 969 | 15 Sterility 滅菌 | TFDA-02103 | ISO | ISO/ASTM 52628:2020 | 2020 | Practice for dosimetry in radiation processing | 109 年度新增採認標準 |
| 970 | 16 Tissue Engineering 組織工程 | TFDA-01105 | ASTM | ASTM F2603-06/(R)2012 | 2012 | Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds | 原採認標準 |
| 971 | 16 Tissue Engineering 組織工程 | TFDA-01748 | ISO | ISO 22442-2 :2015 | 2015 | Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling | 原採認標準 |
| 972 | 16 Tissue Engineering 組織工程 | TFDA-01749 | ISO | ISO 22442-3:2007 | 2007 | Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents | 原採認標準 |
| 973 | 16 Tissue Engineering 組織工程 | TFDA-01868 | ASTM | ASTM F2064-17 | 2017 | Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Products Application | 原採認標準 |

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| 974 | 16 Tissue Engineering 組織工程 | TFDA-01869 | ASTM | ASTM F3206-17 | 2017 | Standard Guide for Assessing Medical Device Cytocompatibility with Delivered Cellular Therapies | 原採認標準 |
| 975 | 16 Tissue Engineering 組織工程 | TFDA-01870 | ASTM | ASTM F3207-17 | 2017 | Standard Guide for in vivo Evaluation of Rabbit Lumbar Intertransverse Process Spinal Fusion Model | 原採認標準 |
| 976 | 16 Tissue Engineering 組織工程 | TFDA-02104 | ASTM | ASTM F3224-17 | 2017 | Standard Test Method for Evaluating Growth of Engineered Cartilage Tissue using Magnetic Resonance Imaging. | 109 年度新增採認標準 |
| 977 | 16 Tissue Engineering 組織工程 | TFDA-02105 | ASTM | ASTM F2212 - 19 | 2019 | Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs) | 109 年度新增採認標準 |
| 978 | 17 Neurology 神經學 | TFDA-00709 | ISO | ISO 7197:2006 ; ISO 7197:2006/Cor 1:2007 | 2007 | Technical Corrigendum1- Neurosurgical implants -- Sterile, single-use hydrocephalus shunts and components | 原採認標準 |
| 979 | 17 Neurology 神經學 | TFDA-01324 | IEC | IEC 60601-2-23:2011 | 2011 | Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment - Edition 3.0 | 原採認標準 |
| 980 | 17 Neurology 神經學 | TFDA-01752 | IEC | IEC 60601-2-10:2016 | 2016 | Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators | 原採認標準 |
| 981 | 17 Neurology 神經學 | TFDA-01926 | ASTM | ASTM F647 - 94(2014) | 2014 | Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application | 原採認標準 |
| 982 | 17 Neurology 神經學 | TFDA-01927 | AAMI | AAMI NS28:1988/(R)2015 | 2015 | Intracranial Pressure Monitoring Devices | 原採認標準 |

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| 983 | 17 Neurology 神經學 | TFDA-01928 | AAMI | AAMI NS4:2013/(R)2017 | 2017 | Transcutaneous electrical nerve stimulators | 原採認標準 |
| 984 | 18 Nanotechnology 奈米科技 | TFDA-01871 | ISO | ISO 29701:2010 | 2010 | Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems—Limulus amebocyte lysate (LAL) test. | 原採認標準 |
| 985 | 18 Nanotechnology 奈米科技 | TFDA-01872 | ISO | ISO/TR 13014:2012+C1:2017 | 2012 | Nanotechnologies—Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment | 原採認標準 |
| 986 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01003 | CNS | CNS 14912 | 2013 | 醫電設備之安全標準規範 (Fundamental aspects of safety standards for medical electrical equipment) | 原採認標準 |
| 987 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01004 | CNS | CNS 14913 | 2013 | 醫電設備之圖形符號 (Graphical symbols for electrical equipment in medical practice) | 原採認標準 |
| 988 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01005 | IEC | IEC 60601-1:2005+Corr1: 2012 | 2012 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Edition 3.1 | 原採認標準 |
| 989 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01007 | IEC | IEC 60601-1-2:2014 ed4.0 | 2014 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests - Edition 4.0 | 原採認標準 |
| 990 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01008 | IEC | IEC 60601-1-6:2013 ed3.1 Consol. with am1 | 2013 | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability - Edition 3.1: Consolidated Reprint | 原採認標準 |

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| 991 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01009 | IEC | IEC 60601-1-8:2012 | 2012 | Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems - Edition 2.1 | 原採認標準 |
| 992 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01011 | IEC | IEC 61326-1:2012 | 2012 | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements - Edition 2.0 | 原採認標準 |
| 993 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01017 | ISO | ISO/TS 19218-2:2012 | 2012 | Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes - First Edition | 原採認標準 |
| 994 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01753 | IEC | IEC 60601-1-10:2008+A1 :2015 | 2015 | Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers | 原採認標準 |
| 995 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01754 | IEC | IEC 60601-1-11:2015 | 2015 | Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment | 原採認標準 |
| 996 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01755 | IEC | IEC 60601-1-12:2014 | 2014 | Medical electrical equipment Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment | 原採認標準 |
| 997 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01757 | IEC | IEC/TR 60601-4-2:2017 | 2017 | Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems | 原採認標準 |

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| 998 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01758 | IEC | IEC/TR 62354:2014 | 2014 | General testing procedures for medical electrical equipment | 原採認標準 |
| 999 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01759 | IEEE | IEEE/ANSI C63.27-2017 | 2017 | American National Standard for Evaluation of Wireless Coexistence | 原採認標準 |
| 1000 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01929 | IEC | IEC/TR 60601-4-1:2017 | 2017 | Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy | 原採認標準 |

**衛生福利部食品藥物管理署醫療器材標準採認公告**

**附件 2、本署過去曾公告採認醫療器材標準清單**

說明:

1. 本清單所列醫療器材標準，為本署過去曾公告採認，然因該項標準已廢除或改版。
2. 109 年度已廢除/改版之醫療器材標準共 220 項(表 一)，104 年度至 108 年度已公告廢除/改版之醫療器材標準共 813 項(表二)。

**表 一、109 年度已廢除/改版之醫療器材標準共 220 項**

| 序號 | 標準類別 | TFDA 採認編號 | 標準組織名稱 | 標準號碼 | 標準版本 | 標準名稱 | 備註說明 |
|---|---|---|---|---|---|---|---|
| 1 | 1 Anesthesias 麻醉學 | TFDA-00572 | CNS | CNS 15003-1 | 2006 | 醫療氣體管線系統－第１部：壓縮醫療氣體及真空用管線 | 原採認標準已廢除 |
| 2 | 1 Anesthesias 麻醉學 | TFDA-00573 | CNS | CNS 15003-2 | 2006 | 醫療氣體管線系統－第２部：麻醉氣體之清理排放系統 | 原採認標準已廢除 |
| 3 | 1 Anesthesias 麻醉學 | TFDA-00575 | CNS | CNS 15005-1 | 2006 | 醫療氣體管線系統之終端單元－第１部：壓縮醫療氣體與真空用終端單元 | 原採認標準已廢除 |
| 4 | 1 Anesthesias 麻醉學 | TFDA-00576 | CNS | CNS 15005-2 | 2006 | 醫療氣體管線系統之終端單元－第２部：麻醉氣體清理系統之終端單元 | 原採認標準已廢除 |
| 5 | 1 Anesthesias 麻醉學 | TFDA-00888 | ASTM | ASTM F1850-00/(R)2005 | 2005 | Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components | 原採認標準已廢除 |
| 6 | 1 Anesthesias 麻醉學 | TFDA-01159 | EN | EN 13544-1:2007+A1: 2009 | 2010 | Respiratory therapy equipment - Part 1: Nebulizing systems and their | 原採認標準已廢除，請參考取代標準。 |

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| | | | | | | components - Incorporates Amendment A1: 2009 | (EN ISO 27427 : 2019) |
| 7 | 1 Anesthesias 麻醉學 | TFDA-01174 | ISO | ISO 80601-2-12:2011 | 2011 | Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators | 本標準已改版，請參考新版本標準。(ISO 80601-2-12:2020) |
| 8 | 1 Anesthesias 麻醉學 | TFDA-01175 | ISO | ISO 80601-2-12:2011/Cor 1:2011 | 2011 | Medical electrical equipment Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators TECHNICAL CORRIGENDUM 1 - First Edition | 本標準已改版，請參考新版本標準。(ISO 80601-2-12:2020) |
| 9 | 1 Anesthesias 麻醉學 | TFDA-01452 | ISO | ISO 80601-2-12:2011/Cor 1:2011 | 2011 | Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications | 本標準已改版，請參考新版本標準。(ISO 80601-2-12:2020) |
| 10 | 1 Anesthesias 麻醉學 | TFDA-01453 | ISO | ISO 10079-1:2015 | 2015 | Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements | 本標準已改版，請參考新版本標準。(ISO 10079-1:2015/AMD 1:2018) |
| 11 | 1 Anesthesias 麻醉學 | TFDA-01469 | ISO | ISO 8836:2014 | 2014 | Suction catheters for use in the respiratory tract | 本標準已改版，請參考新版本標準。(ISO 8836:2019) |
| 12 | 1 Anesthesias 麻醉學 | TFDA-01764 | IEC | IEC 80601-2-13:2018 | 2018 | Medical electrical equipment - Part | 本標準已改版，請參考新版 |

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| | | | | | | 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation | 本標準。(ISO 80601-2-13:2011/Amd 2:2018) |
| 13 | 1 Anesthesias 麻醉學 | TFDA-01769 | ISO | ISO 5356-2:2012 | 2012 | Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors | 本標準已改版，請參考新版本標準。(ISO 5356-2:2012/AMD 1:2019) |
| 14 | 2 Biocompatibility 生物相容性 | TFDA-00022 | ISO | ISO 10993-15:2000 | 2000 | Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals an | 本標準已改版，請參考新版本標準。(ISO 10993-15:2019) |
| 15 | 2 Biocompatibility 生物相容性 | TFDA-00346 | ISO | ISO 10993-18:2005 | 2005 | Biological evaluation of medical devices —Part 18: Chemical characterization of materials | 本標準已改版，請參考新版本標準。(ISO 10993-18:2020) |
| 16 | 2 Biocompatibility 生物相容性 | TFDA-00347 | ISO | ISO/TS 10993-19:2006 | 2006 | Biological evaluation of medical devices —Part 19: Physico-chemical, morphological and topographical characterization of materials | 本標準已改版，請參考新版本標準。(ISO/TS 10993-19:2020) |
| 17 | 2 Biocompatibility 生物相容性 | TFDA-00859 | ISO | ISO 10993-9:2009 | 2009 | Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products | 本標準已改版，請參考新版本標準。(ISO 10993-9:2019) |

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| 18 | 2 Biocompatibility 生物相容性 | TFDA-01019 | ASTM | ASTM F719-81/(R)2012 | 2012 | Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation | 本標準已改版，請參考新版本標準。(ASTM F719 - 20) |
| 19 | 2 Biocompatibility 生物相容性 | TFDA-01021 | ASTM | ASTM F749-13 | 2013 | Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit | 本標準已改版，請參考新版本標準。(ASTM F749 - 20) |
| 20 | 2 Biocompatibility 生物相容性 | TFDA-01025 | ISO | ISO 10993-7:2008/Cor 1:2009 | 2009 | Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals | 本標準已改版，請參考新版本標準。(ISO 10993-7:2008/Amd 1:2019) |
| 21 | 2 Biocompatibility 生物相容性 | TFDA-01774 | ASTM | ASTM F2382-17 | 2017 | Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT) | 本標準已改版，請參考新版本標準。(ASTM F2382 - 18) |
| 22 | 3 Cardiovascular 心臟血管醫學 | TFDA-01178 | AAMI | AAMI EC12:2000/(R)2010 | 2010 | Disposable ECG electrodes | 本標準已改版，請參考新版本標準。(AMMI EC12:2000/(R2015)) |
| 23 | 3 Cardiovascular 心臟血管醫學 | TFDA-01182 | AAMI | AAMI/ISO 14117:2012 | 2012 | Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices. | 本標準已改版，請參考新版本標準。(AAMI/ISO 14117:2019) |
| 24 | 3 Cardiovascular 心臟 | TFDA-01183 | AAMI | IEC 60601-2-25:2011 | 2011 | Medical electrical equipment - Part | 本標準已改版，請參考新版 |

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| | 血管醫學 | | | | | 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs. | 本標準。(IEC 60601-2-25:2011(R2016)) |
| 25 | 3 Cardiovascular 心臟血管醫學 | TFDA-01184 | ASTM | ASTM F2081-06/(R)2013 | 2013 | Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents | 本標準已改版，請參考新版本標準。(ASTM F2081 - 06(2017)) |
| 26 | 3 Cardiovascular 心臟血管醫學 | TFDA-01186 | ASTM | ASTM F1984-99/(R)2008 | 2008 | Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials | 本標準已改版，請參考新版本標準。(ASTM F1984 - 99(2018)) |
| 27 | 3 Cardiovascular 心臟血管醫學 | TFDA-01188 | ASTM | ASTM F2065-00e1/(R)2010 | 2010 | Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials | 原採認標準已廢除 |
| 28 | 3 Cardiovascular 心臟血管醫學 | TFDA-01189 | ASTM | ASTM F2079-09 | 2009 | Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon Expandable Stents | 本標準已改版，請參考新版本標準。(ASTM F2079 - 09(2017)) |
| 29 | 3 Cardiovascular 心臟血管醫學 | TFDA-01192 | ASTM | ASTM F2394-07 | 2007 | Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System | 本標準已改版，請參考新版本標準。(ASTM F2394 - 07(2017)) |
| 30 | 3 Cardiovascular 心臟血管醫學 | TFDA-01193 | ASTM | ASTM F746-04/(R)2009e1 | 2009 | Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials | 本標準已改版，請參考新版本標準。(ASTM F746 - 04(2014)) |
| 31 | 3 Cardiovascular 心臟 | TFDA-01194 | ASTM | ASTM G71-81/(R)2009 | 2009 | Standard Guide for Conducting and | 本標準已改版，請參考新版 |

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| | 血管醫學 | | | | | Evaluating Galvanic Corrosion Tests in Electrolytes | 本標準。(ASTM G71 - 81(2019)) |
| 32 | 3 Cardiovascular 心臟血管醫學 | TFDA-01199 | CNS | CNS 14509-2-49 | 2014 | 醫電設備－第 2-49 部:多功能患者監視設備安全之個別規定 Medical electrical equipment − Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IDT: IEC 61267:2005) | 原採認標準已廢除 |
| 33 | 3 Cardiovascular 心臟血管醫學 | TFDA-01202 | IEC | IEC 60601-2-31:2011 ed2.1 Consol. with am1 | 2011 | Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source | 本標準已改版，請參考新版本標準。(IEC 60601-2-31:2020 ) |
| 34 | 3 Cardiovascular 心臟血管醫學 | TFDA-01209 | ISO | ISO 14708-2:2012 | 2012 | Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers | 本標準已改版，請參考新版本標準。(ISO 14708-2:2019) |
| 35 | 3 Cardiovascular 心臟血管醫學 | TFDA-01476 | ASTM | ASTM F138-13 | 2013 | Standard Specification for Wrought 18 Chromium 14 Nickel 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673) | 本標準已改版，請參考新版本標準。(ASTM F138 - 19) |
| 36 | 3 Cardiovascular 心臟血管醫學 | TFDA-01480 | ASTM | ASTM F2942-13 | 2013 | Standard Guide for in vitro Axial, Bending, and Torsional Durability | 本標準已改版，請參考新版本標準。(ASTM F2942 - 19) |

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| | | | | | | Testing of Vascular Stents | |
| 37 | 3 Cardiovascular 心臟血管醫學 | TFDA-01483 | ISO | ISO 15674:2016 | 2016 | Cardiovascular implants and artificial organs - Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags | 本標準已改版，請參考新版本標準。(ISO 15674:2016/AMD 1:2020) |
| 38 | 3 Cardiovascular 心臟血管醫學 | TFDA-01484 | ISO | ISO 15675:2016 | 2016 | Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters | 本標準已改版，請參考新版本標準。(ISO 15675:2016/AMD 1:2020) |
| 39 | 3 Cardiovascular 心臟血管醫學 | TFDA-01491 | ISO | ISO 7199:2016 | 2016 | Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) | 本標準已改版，請參考新版本標準。(ISO 7199:2016/AMD 1:2020) |
| 40 | 3 Cardiovascular 心臟血管醫學 | TFDA-01493 | ISO | ISO/TS 17137:2014 | 2014 | Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants | 本標準已改版，請參考新版本標準。(ISO/TS 17137:2019) |
| 41 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00872 | ISO | ISO 4049:2009 | 2009 | Dentistry -- Polymer-based restorative materials | 本標準已改版，請參考新版本標準。(ISO 4049:2019) |
| 42 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01227 | CNS | CNS 14496 | 2012 | 牙科材料-牙用聚合材料顏色穩定性的測定 (Dental materials-Determination of color stability of dental polymeric aterials) | 原採認標準已廢除 |
| 43 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01239 | IEC | IEC 80601-2-60:2012 ed1.0 | 2012 | Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential | 本標準已改版，請參考新版本標準。(IEC 80601-2-60:2019 ) |

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| | | | | | | performance of dental equipment | |
| 44 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01240 | ASA | ASA S3.6 (2010) | 2010 | American National Standard Specification for Audiometers | 本標準已改版，請參考新版本標準。(ASA S3.6-2018) |
| 45 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01495 | ASA | ASA S3.22 (2014) | 2014 | Specification of Hearing Aid Characteristics | 本標準已改版，請參考新版本標準。(ASA S3.22-2014 (R2020)) |
| 46 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01496 | IEC | IEC 60601-2-66:2015 | 2015 | Medical electrical equipment Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument system | 本標準已改版，請參考新版本標準。(IEC 60601-2-66:2019) |
| 47 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01501 | ISO | ISO 6872:2015 | 2015 | Dentistry - Ceramic materials | 本標準已改版，請參考新版本標準。(ISO 6872:2015/AMD 1:2018) |
| 48 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01503 | ISO | ISO 9693-1:2012 | 2012 | Dentistry — Compatibility testing — Part 1: Metal-ceramic systems - First Edition | 原採認標準已廢除，請參考取代標準。(ISO 9693:2019) |
| 49 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00442 | CNS | CNS15013 | 2006 | 用於法規目的之醫療器材品質管理系統要求 | 原採認標準已廢除 |
| 50 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00695 | ISO | ISO 14971:2007 | 2007 | Medical devices -- Application of risk management to medical devices | 本標準已改版，請參考新版本標準。(ISO 14971:2019) |
| 51 | 5 General I (QS/RM) 通 | TFDA-00958 | AAMI | AAMI HE75:2009 | 2009 | Human factors engineering - Design | 本標準已改版，請參考新版 |

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| | 用(品質管理系統/風險管理) | | | | | of medical devices | 本標準。(AAMI HE75:2009(R2018)) |
| 52 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01015 | ISO | ISO/TR 24971:2013 | 2013 | Medical devices — Guidance on the application of ISO 14971 | 本標準已改版，請參考新版本標準。(ISO/TR 24971:2020) |
| 53 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01506 | CNS | CNS 14509-1-6 | 2015 | 醫電設備－第 1-6 部：基本安全與必要性能之一般要求－附屬標準:可用性(Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability) | 原採認標準已廢除 |
| 54 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01508 | IEC | IEC 62366-1:2015/COR1:2016 | 2016 | Medical devices –Part 1: Application of usability engineering to medical devices | 本標準已改版，請參考新版本標準。(IEC 62366-1:2015+AMD1:2020) |
| 55 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01515 | ISO | ISO 80369-3:2016 | 2016 | Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications | 本標準已改版，請參考新版本標準。(ISO 80369-3:2016/AMD 1:2019) |
| 56 | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01516 | ISO | ISO 80369-5:2016 | 2016 | Small-bore connectors for liquids and gases in healthcare applications—Part 5: Connectors for limb cuff inflation applications | 本標準已改版，請參考新版本標準。(IEC 80369-5:2016/COR 1:2017) |
| 57 | 6 General Plastic | TFDA-00121 | ISO | ISO 7886-2:1996 | 1996 | Sterile Hypodermic Syringes for | 本標準已改版，請參考新版 |

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| | Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | Single Use - Part 2: Syringes for use with Power-Driven Syringe Pumps | 本標準。(ISO 7886-2:2020) |
| 58 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00309 | CNS | CNS 14509 | 2012 | 醫電設備電性安全－第 1 部：一般安全規定 Medical Electrical Equipment--Part 1: General Requirements for Safety (IDE IEC 60601-1:1988) | 原採認標準已廢除 |
| 59 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00310 | CNS | CNS 14509-1 | 2013 | 醫電設備電性安全－第一部分：一般安全規定－附屬標準 1：醫電系統之安全規定 Medical Electrical Equipment--Part 1-1: General Requirements for Safety-Collateral Standard: Safety Requirements for Medical Electrical systems (IDE IEC 60601-1-1) | 原採認標準已廢除 |
| 60 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00311 | CNS | CNS 14509-2 | 2013 | 醫電設備電性安全－第一部分：一般安全規定－附屬標準 2：電磁相容性之規定與測試 Medical Electrical Equipment--Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic | 原採認標準已廢除 |

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| | | | | | | Compatibility-Requirements and Tests (IDE IEC 60601-1-2) | |
| 61 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00312 | CNS | CNS 14509-4 | 2013 | 醫電設備電性安全－第一部分：一般安全規定－附屬標準 4：可程式化醫電系統 Medical Electrical Equipment--Part 1-4: General Requirements for Safety-Collateral Standard: Programmable Electrical Medical Systems (IDE IEC 60601-1-4) | 原採認標準已廢除 |
| 62 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00458 | ISO | ISO 7886-3:2005 | 2005 | Sterile hypodermic syringes for single use -- Part 3: Auto-disable syringes for fixed-dose immunization | 本標準已改版，請參考新版本標準。(ISO 7886-3:2020) |
| 63 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00591 | CNS | CNS 14624-1 | 2002 | 醫療用輸液設備－第一部分：玻璃點滴瓶 | 原採認標準已廢除 |
| 64 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個 | TFDA-00594 | CNS | CNS 14624-4 | 2002 | 醫療用輸液設備—第四部份：單次使用之重力式輸液套 | 原採認標準已廢除 |

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| | 人使用裝置 | | | | | | |
| 65 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00595 | CNS | CNS 14624-5 | 2002 | 醫療用輸液設備一第五部份：量管型輸液套 | 原採認標準已廢除 |
| 66 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00596 | CNS | CNS 14624-6 | 2002 | 醫療用輸液設備一第六部份：點滴瓶之凍晶乾燥瓶塞 | 原採認標準已廢除 |
| 67 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00597 | CNS | CNS 14624-7 | 2002 | 醫療用輸液設備一第七部份：鋁一塑膠組合成之點滴瓶蓋 | 原採認標準已廢除 |
| 68 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00718 | ASTM | ASTM F881-94/(R)2006 | 2006 | Standard Specification for Silicone Elastomer Facial Implants | 本標準已改版，請參考新版本標準。(ASTM F881 - 94(2014)) |
| 69 | 6 General Plastic Surgery/General Hospital 一般及整形外 | TFDA-00916 | ASTM | ASTM F1441-03/(R)2009 | 2009 | Standard Specification for Soft-Tissue Expander Devices | 本標準已改版，請參考新版本標準。(ASTM F1441 - 03(2014)) |

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| | 科手術/一般醫院及個人使用裝置 | | | | | | |
| 70 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00923 | ASTM | ASTM F754 - 08 | 2008 | Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders | 本標準已改版，請參考新版本標準。(ASTM F754 - 08(2015) ) |
| 71 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00929 | ASTM | ASTM E1104-98/(R)2009 | 2009 | Standard Specification for Clinical Thermometer Probe Covers and Sheaths | 本標準已改版，請參考新版本標準。(ASTM E1104 - 98(2016)) |
| 72 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00930 | ASTM | ASTM E1965-98/(R)2009 | 2009 | Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature | 本標準已改版，請參考新版本標準。(ASTM E1965 - 98(2016)) |
| 73 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00984 | CEN | EN 455-1:2000 | 2000 | Medical gloves for single use —Part 1: Requirements and testing for freedom from holes | 本標準已改版，請參考新版本標準。(EN 455-1:2020) |
| 74 | 6 General Plastic Surgery/General | TFDA-01258 | AAMI | AAMI BP22:1994/(R)2011 | 2011 | Blood pressure transducers | 本標準已改版，請參考新版本標準。(AAMI |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | | BP22:1994/(R2016)) |
| 75 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01260 | ASTM | ASTM D3577-09/(E)2009 | 2009 | Standard Specification for Rubber Surgical Gloves | 本標準已改版，請參考新版本標準。(ASTM D3577 - 19) |
| 76 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01261 | ASTM | ASTM D3578-05/(R)2010 | 2010 | Standard Specification for Rubber Examination Gloves | 本標準已改版，請參考新版本標準。(ASTM D3578 - 19) |
| 77 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01263 | ASTM | ASTM D5151-06/(R)2011 | 2011 | Standard Test Method for Detection of Holes in Medical Gloves | 本標準已改版，請參考新版本標準。(ASTM D5151 - 19) |
| 78 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01264 | ASTM | ASTM D6124-06/(R)2011 | 2011 | Standard Test Method for Residual Powder on Medical Gloves | 本標準已改版，請參考新版本標準。(ASTM D6124 - 06(2017)) |
| 79 | 6 General Plastic | TFDA-01265 | ASTM | ASTM D6355-07/(R)2012 | 2012 | Standard Test Method for Human | 本標準已改版，請參考新版 |

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| | Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | Repeat Insult Patch Testing of Medical Gloves | 本標準。(ASTM D6355 - 07(2017)) |
| 80 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01267 | ASTM | ASTM D6978-05/(R)2013 | 2013 | Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs | 本標準已改版，請參考新版本標準。(ASTM D6978 - 05(2019)) |
| 81 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01270 | ASTM | ASTM E1112-00/(R)2011 | 2011 | Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature | 本標準已改版，請參考新版本標準。(ASTM E1112 - 00(2018) ) |
| 82 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01277 | ASTM | ASTM F2182-11a | 2011 | Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging | 本標準已改版，請參考新版本標準。(ASTM F2182 - 19e2) |
| 83 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01279 | ASTM | ASTM F2503-13 | 2013 | Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment | 本標準已改版，請參考新版本標準。(ASTM F2503 - 20) |

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| 84 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01282 | ASTM | ASTM F899-12 | 2012 | Standard Specification for Wrought Stainless Steels for Surgical Instruments | 本標準已改版，請參考新版本標準。(ASTM F899 - 20) |
| 85 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01284 | CEN | EN 13795:2011+A1:2013 | 2013 | Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels | 原採認標準已廢除，請參考取代標準。(EN 13795-1, EN 13795-2) |
| 86 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01311 | ISO | ISO 8536-4:2010/Amd 1:2013 | 2013 | Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed | 本標準已改版，請參考新版本標準。(ISO 8536-4:2019) |
| 87 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01314 | ASTM | ASTM A908-03/(R)2013 | 2013 | Standard Specification for Stainless Steel Needle Tubing | 本標準已改版，請參考新版本標準。(ASTM A908 - 03(2019)) |
| 88 | 6 General Plastic Surgery/General | TFDA-01315 | ASTM | ASTM D5250-06/(R)2011 | 2011 | Standard Specification for Poly(vinyl chloride) Gloves for Medical | 本標準已改版，請參考新版本標準。(ASTM D5250 - |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | Application | 19 ) |
| 89 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01317 | CNS | CNS 14509-2-59 | 2014 | 醫電設備－第 2-59 部:人體發燒體溫篩檢熱影像儀之基本安全與必要性能之個別規定 Medical electrical equipment Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IDT: IEC 80601-2-59:2008) | 原採認標準已廢除 |
| 90 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01525 | ASTM | ASTM F2710-13 | 2013 | Standard Consumer Safety Performance Specification for Commercial Cribs | 本標準已改版，請參考新版本標準。(ASTM F2710 - 19) |
| 91 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01549 | ISO | ISO 80601-2-56:2017 | 2017 | Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement | 本標準已改版，請參考新版本標準。(ISO 80601-2-56:2017/AMD 1:2018) |
| 92 | 6 General Plastic Surgery/General | TFDA-01798 | ASTM | ASTM F1670/F1670M:2017 | 2017 | Standard Test Method for Resistance of Materials Used in Protective | 本標準已改版，請參考新版本標準。(ASTM F1670 / |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | Clothing to Penetration by Synthetic Blood | F1670M - 17a) |
| 93 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01873 | ISO | ISO 11193-1:2008 | 2008 | Single-Use Medical Examination Gloves - Part 1: Specification for Gloves Made from Rubber Latex or Rubber Solution | 本標準已改版，請參考新版本標準。(ISO 11193-1:2008/AMD 1:2012) |
| 94 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01874 | ASTM | ASTM D6319-10 | 2010 | Standard Specification for Nitrile Examination Gloves for Medical Application | 本標準已改版，請參考新版本標準。(ASTM D6319 - 19) |
| 95 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00211 | CLSI | H51-A | 2002 | Assays of vonWillebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline | 原採認標準已廢除 |
| 96 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00320 | ISO | ISO 17511:2003 | 2003 | In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials | 本標準已改版，請參考新版本標準。(ISO 17511:2020) |
| 97 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00325 | ISO | ISO/TR 18112:2006 | 2006 | Clinical laboratory testing and in vitro diagnostic test systems─In vitro diagnostic medical devices for | 原採認標準已廢除 |

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| | | | | | | professional use─Summary of regulatory requirements for information supplied by the manufacturer | |
| 98 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00502 | CLSI | M21-A | 1999 | Methodology for the Serum Bactericidal Test; Approved Guideline | 原採認標準已廢除 |
| 99 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00509 | CLSI | M32-P | 2001 | Evaluation of Lots of Dehydrated Mueller-Hinton Broth for Antimicrobial Susceptibility Testing; Proposed Guideline | 原採認標準已廢除 |
| 100 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00666 | CLSI | GP27-A2 | 2007 | Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline - Second Edition | 原採認標準已廢除 |
| 101 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00848 | CLSI | C49-A | 2007 | Analysis of Body Fluids in Clinical Chemistry; Approved Guideline | 本標準已改版，請參考新版本標準。(C49) |
| 102 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00946 | CLSI | MM16-A | 2006 | Use of External RNA Controls in Gene Expression Assays; Approved Guideline | 原採認標準已廢除 |
| 103 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01114 | CLSI | EP09-A3 | 2013 | Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition | 本標準已改版，請參考新版本標準。(EP09c) |
| 104 | 7 In Vitro Diagnostics | TFDA-01118 | CLSI | GP22-A3 | 2011 | Quality Management System: | 原採認標準已廢除 |

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| | 體外診斷醫療器材 | | | | | Continual Improvement; Approved Guideline—Third Edition | |
| 105 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01125 | CLSI | M27-S4 | 2012 | Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement | 本標準已改版，請參考新版本標準。(M27) |
| 106 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01135 | CLSI | VET01-A4 | 2013 | Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard—Fourth Edition | 本標準已改版，請參考新版本標準。(VET01) |
| 107 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01152 | ISO | ISO 20776-1:2006 | 2006 | Clinical laboratory testing and in vitro diagnostic test systems Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases - First Edition | 本標準已改版，請參考新版本標準。(ISO 20776-1:2019) |
| 108 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01576 | IEC | IEC 61010-1:2017 | 2017 | Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General | 本標準已改版，請參考新版本標準。(IEC 61010-1:2010/AMD1:2016/ |

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| 109 | 8 Materials 材料 | TFDA-00065 | ISO | ISO 13782:1996 | 1996 | Implants for surgery -- Metallic materials -- Unalloyed tantalum for surgical implant applications | 本標準已改版，請參考新版本標準。(ISO 13782:2019) |
| 110 | 8 Materials 材料 | TFDA-00073 | ISO | ISO 5832-8:1997 | 1997 | Implants for surgery -- Metallic materials -- Part 8: Wrought cobalt-nickel-chromium-molybdenum- tungsten-iron alloy | 原採認標準已廢除 |
| 111 | 8 Materials 材料 | TFDA-00556 | CNS | CNS 13382-18 | 1995 | 外科植入物–生物相容性–材料及器材之生物檢測方法的選擇（準則） | 原採認標準已廢除 |
| 112 | 8 Materials 材料 | TFDA-00562 | CNS | CNS 13382-24 | 1996 | 外科植入物–超高分子量聚乙烯（第一部分：粉狀） | 原採認標準已廢除 |
| 113 | 8 Materials 材料 | TFDA-00563 | CNS | CNS 13382-25 | 1996 | 外科植入物–超高分子量聚乙烯（第二部分：成形材） | 原採認標準已廢除 |
| 114 | 8 Materials 材料 | TFDA-00952 | AAMI | ST65:2008 | 2008 | Processing of reusable surgical textiles for use in health care facilities | 本標準已改版，請參考新版本標準。(AAMI ST65:2008 (R2018)) |
| 115 | 8 Materials 材料 | TFDA-00956 | ISO | ISO 13938-1:1999 | 1999 | Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension | 本標準已改版，請參考新版本標準。(ISO 13938-1:2019) |
| 116 | 8 Materials 材料 | TFDA-01087 | ASTM | ASTM F1091-12 | 2012 | Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10 Nickel Alloy Surgical Fixation Wire | 本標準已改版，請參考新版本標準。(ASTM F1091 - 20) |

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| 117 | 8 Materials 材料 | TFDA-01089 | ASTM | ASTM F139-12 | 2012 | Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673) | 本標準已改版，請參考新版本標準。(ASTM F139 - 19) |
| 118 | 8 Materials 材料 | TFDA-01090 | ASTM | ASTM F1537-11 | 2011 | Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) | 本標準已改版，請參考新版本標準。(ASTM F1537 - 20) |
| 119 | 8 Materials 材料 | TFDA-01094 | ASTM | ASTM F2393-12 | 2012 | Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications | 本標準已改版，請參考新版本標準。(ASTM F2393 - 12(2016)) |
| 120 | 8 Materials 材料 | TFDA-01097 | ASTM | ASTM F621-12 | 2012 | Standard Specification for Stainless Steel Forgings for Surgical Implants | 本標準已改版，請參考新版本標準。(ASTM F621 - 12(2017)) |
| 121 | 8 Materials 材料 | TFDA-01098 | ASTM | ASTM F899-12b | 2012 | Standard Specification for Wrought Stainless Steels for Surgical Instruments | 本標準已改版，請參考新版本標準。(ASTM F899 - 20) |
| 122 | 8 Materials 材料 | TFDA-01585 | ASTM | ASTM F1581-08/(R)2012 | 2012 | Standard Specification for Composition of Anorganic Bone for Surgical Implants | 本標準已改版，請參考新版本標準。(ASTM F1581 - 08(2016) ) |

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| 123 | 8 Materials 材料 | TFDA-01809 | ASTM | ASTM F2129-17 | 2017 | Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices | 本標準已改版，請參考新版本標準。(ASTM F2129 - 19a ) |
| 124 | 8 Materials 材料 | TFDA-01811 | ASTM | ASTM F3208-17 | 2017 | Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices. | 本標準已改版，請參考新版本標準。(ASTM F3208 - 19) |
| 125 | 8 Materials 材料 | TFDA-01812 | ASTM | ASTM F3260-17 | 2017 | Standard Test Method for Determining the Flexural Stiffness of Medical Textiles | 本標準已改版，請參考新版本標準。(ASTM F3260 - 18) |
| 126 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00912 | ISO | ISO 8638:2010 | 2010 | Cardiovascular implants and extracorporeal systems -- Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters | 原採認標準已廢除，請參考取代標準。(ISO 8637-2:2018) |
| 127 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00914 | AAMI | AAMI RD47:2008/(R)2013 | 2013 | Reprocessing of hemodialyzers | 本標準已改版，請參考新版本標準。(AAMI RD47-2020) |
| 128 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學 | TFDA-01243 | ISO | ISO 13959:2014 | 2014 | Water for haemodialysis and related therapies - Third Edition | 原採認標準已廢除，請參考取代標準。(ISO 23500-3:2019) |

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| 129 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01244 | ISO | ISO 26722:2014 | 2014 | Water treatment equipment for haemodialysis applications and related therapies - Second Edition | 原採認標準已廢除，請參考取代標準。(ISO 23500-2:2019) |
| 130 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01246 | AAMI | AAMI 23500:2014 | 2014 | Guidance for the preparation and quality management of fluids for hemodialysis and related therapies | 原採認標準已廢除，請參考取代標準。(AAMI 23500-1:2019) |
| 131 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01606 | EN | EN 1618:1997 | 1997 | Catheters Other than Intravascular Catheters - Test Methods for Common Properties | 原採認標準已廢除，請參考取代標準。(EN ISO 20695:2020) |
| 132 | 10 Ophthalmic 眼科學 | TFDA-01339 | ISO | ISO 11979-9:2006/Amd 1:2014 | 2014 | Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses AMENDMENT 1 - First Edition | 原採認標準已廢除，請參考取代標準。(ISO 11979-7:2018) |
| 133 | 11 Orthopaedics 骨科學 | TFDA-00547 | CNS | CNS 13382-9 | 1995 | 外科植入物–骨髓內釘系統（第二部分：骨髓釘） | 原採認標準已廢除 |
| 134 | 11 Orthopaedics 骨科學 | TFDA-00548 | CNS | CNS 13382-10 | 1995 | 外科植入物–骨科人工關節–基本需求 | 原採認標準已廢除 |
| 135 | 11 Orthopaedics 骨科學 | TFDA-00549 | CNS | CNS 13382-11 | 1995 | 外科植入物–半人工及全人工膝關節（第一部分：分類、定義及尺寸之標示） | 原採認標準已廢除 |

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| 136 | 11 Orthopaedics 骨科學 | TFDA-00550 | CNS | CNS 13382-12 | 1995 | 外科植入物–金屬骨螺絲具有六角螺絲頭螺絲之起子接觸帽孔，球形之螺帽下表面，不對稱之螺紋–尺寸 | 原採認標準已廢除 |
| 137 | 11 Orthopaedics 骨科學 | TFDA-00551 | CNS | CNS 13382-13 | 1995 | 外科植入物–具錐形下表面螺絲頭之金屬骨螺絲–尺寸 | 原採認標準已廢除 |
| 138 | 11 Orthopaedics 骨科學 | TFDA-00552 | CNS | CNS 13382-14 | 1995 | 外科植入物–聚甲基丙烯酸甲脂第一部分: 骨科應用 | 原採認標準已廢除 |
| 139 | 11 Orthopaedics 骨科學 | TFDA-00553 | CNS | CNS 13382-15 | 1995 | 外科植入物–金屬骨板–螺絲孔適用不對稱螺紋及球形下表面之螺絲 | 原採認標準已廢除 |
| 140 | 11 Orthopaedics 骨科學 | TFDA-00554 | CNS | CNS 13382-16 | 1995 | 外科植入物–金屬骨板–螺絲孔及槽適用於錐形下表面螺絲 | 原採認標準已廢除 |
| 141 | 11 Orthopaedics 骨科學 | TFDA-00555 | CNS | CNS 13382-17 | 1995 | 外科植入物–骨髓內釘系統–第一部分：橫斷面為梅花狀或V型之骨髓內釘 | 原採認標準已廢除 |
| 142 | 11 Orthopaedics 骨科學 | TFDA-00557 | CNS | CNS 13382-19 | 1995 | 外科植入物–骨板彎曲強度與勁度的測定 | 原採認標準已廢除 |
| 143 | 11 Orthopaedics 骨科學 | TFDA-00558 | CNS | CNS 13382-20 | 1995 | 外科植入物–半及全人工髖關節–第一部分：分類、尺寸標示及規定 | 原採認標準已廢除 |
| 144 | 11 Orthopaedics 骨科學 | TFDA-00559 | CNS | CNS 13382-21 | 1995 | 外科植入物–半及全人工髖關節–第二部分：由金屬及塑膠製成之軸承面 | 原採認標準已廢除 |
| 145 | 11 Orthopaedics 骨科學 | TFDA-00560 | CNS | CNS 13382-22 | 1995 | 外科植入物–半及全人工髖關節–第三部分：不含扭力之股骨柄耐久性測試 | 原採認標準已廢除 |

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| 146 | 11 Orthopaedics 骨科學 | TFDA-00561 | CNS | CNS 13382-23 | 1995 | 外科植入物–半及全人工髖關節–第四部分：含扭力之股骨柄耐久性測試 | 原採認標準已廢除 |
| 147 | 11 Orthopaedics 骨科學 | TFDA-00564 | CNS | CNS 13382-26 | 1996 | 外科植入物–骨針及骨線（第一部分：材料與機械特性要求） | 原採認標準已廢除 |
| 148 | 11 Orthopaedics 骨科學 | TFDA-00565 | CNS | CNS 13382-27 | 1996 | 外科植入物–骨針及骨線（第二部分：Ｓｔｅｉｎｍａｎｎ骨針–尺度） | 原採認標準已廢除 |
| 149 | 11 Orthopaedics 骨科學 | TFDA-00566 | CNS | CNS 13382-28 | 1996 | 外科植入物–骨科使用之平行腳U形釘（一般要求） | 原採認標準已廢除 |
| 150 | 11 Orthopaedics 骨科學 | TFDA-00567 | CNS | CNS 13382-29 | 1996 | 外科植入物–不對稱螺紋與球形底面之金屬骨螺釘（機械要求及測試方法） | 原採認標準已廢除 |
| 151 | 11 Orthopaedics 骨科學 | TFDA-00568 | CNS | CNS 13382-30 | 1996 | 外科植入物–成人之股骨端固定用裝置 | 原採認標準已廢除 |
| 152 | 11 Orthopaedics 骨科學 | TFDA-01354 | ASTM | ASTM F2267-04a/(R)2011 | 2011 | Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression | 本標準已改版，請參考新版本標準。(ASTM F2267 - 04(2018)) |
| 153 | 11 Orthopaedics 骨科學 | TFDA-01356 | ASTM | ASTM F2789-10 | 2010 | Standard Guide for Mechanical and Functional Characterization of Nucleus Devices | 本標準已改版，請參考新版本標準。(ASTM F2789 - 10(2020)) |
| 154 | 11 Orthopaedics 骨科學 | TFDA-01368 | ASTM | ASTM F1714-96/(R)2013 | 2013 | Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip | 本標準已改版，請參考新版本標準。(ASTM |

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| | | | | | | Designs in Simulator Devices. | F1714-96/(R)2018) |
| 155 | 11 Orthopaedics 骨科學 | TFDA-01371 | ASTM | ASTM F2009-00/(R)2011 | 2011 | Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses | 本標準已改版，請參考新版本標準。(ASTM F2009 - 20) |
| 156 | 11 Orthopaedics 骨科學 | TFDA-01375 | ASTM | ASTM F2381-10 | 2010 | Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy | 本標準已改版，請參考新版本標準。(ASTM F2381 - 19) |
| 157 | 11 Orthopaedics 骨科學 | TFDA-01376 | ASTM | ASTM F2423-11 | 2011 | Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses. | 本標準已改版，請參考新版本標準。(ASTM F2423 - 11(2016) ) |
| 158 | 11 Orthopaedics 骨科學 | TFDA-01379 | ASTM | ASTM F2624-12 | 2012 | Standard test method for static, dynamic, and wear assessment of extradiscal single level spinal constructs. | 本標準已改版，請參考新版本標準。(ASTM F2624 - 12(2016)) |
| 159 | 11 Orthopaedics 骨科學 | TFDA-01381 | ASTM | ASTM F2943-14 | 2014 | Standard Guide for Presentation of End User Labeling Information for Orthopedic Implants Used in Joint Arthroplasty. | 本標準已改版，請參考新版本標準。(ASTM F2943 - 14(2019)) |
| 160 | 11 Orthopaedics 骨科學 | TFDA-01620 | ASTM | ASTM F1357-14 | 2014 | Standard Specification for Articulating Total Wrist Implants | 本標準已改版，請參考新版本標準。(ASTM F1357 - |

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| 161 | 11 Orthopaedics 骨科學 | TFDA-01621 | ASTM | ASTM F1611-00/(R)2013 | 2013 | Standard Specification for Intramedullary Reamers | 本標準已改版，請參考新版本標準。(ASTM F1611 - 20) |
| 162 | 11 Orthopaedics 骨科學 | TFDA-01628 | ASTM | ASTM F2385-15 | 2015 | Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs | 本標準已改版，請參考新版本標準。(ASTM F2385 - 15(2019)) |
| 163 | 11 Orthopaedics 骨科學 | TFDA-01638 | ISO | ISO 14243-3: 2014 | 2014 | Implants for surgery - Wear of total knee-joint prostheses - Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test - Second Edition | 本標準已改版，請參考新版本標準。(ISO 14243-3:2014/AMD 1:2020) |
| 164 | 11 Orthopaedics 骨科學 | TFDA-01834 | ASTM | ASTM E399-17 | 2017 | Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness KIc of Metallic Materials | 本標準已改版，請參考新版本標準。(ASTM E399 - 20) |
| 165 | 11 Orthopaedics 骨科學 | TFDA-01835 | ASTM | ASTM F1378-17 | 2017 | Standard Specification for Shoulder Prostheses | 本標準已改版，請參考新版本標準。(ASTM F1378 - 18e1) |
| 166 | 11 Orthopaedics 骨科學 | TFDA-01837 | ASTM | ASTM F1717-15 | 2015 | Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model | 本標準已改版，請參考新版本標準。(ASTM F1717 - 18 ) |

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| 167 | 11 Orthopaedics 骨科學 | TFDA-01841 | ASTM | ASTM F2077-17 | 2017 | Test Methods For Intervertebral Body Fusion Devices | 本標準已改版，請參考新版本標準。(ASTM F2077 - 18) |
| 168 | 12 Physical Medicine 物理醫學科學 | TFDA-00828 | CNS | CNS 14964-23 | 2007 | 輪椅－第 23 部：介護者操作爬梯裝置之要求與測試方法 | 原採認標準已廢除，請參考取代標準。(CNS 14964-28) |
| 169 | 12 Physical Medicine 物理醫學科學 | TFDA-00829 | CNS | CNS 14964-24 | 2007 | 輪椅－第 24 部：使用者操作爬梯裝置之要求與測試方法 | 原採認標準已廢除，請參考取代標準。(CNS 14964-28) |
| 170 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01053 | AAMI | AAMI TIR45:2012 | 2012 | Guidance on the use of AGILE practices in the development of medical device software | 本標準已改版，請參考新版本標準。(AAMI TIR45:2012/(R)2018) |
| 171 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01058 | ASTM | ASTM F2761-09 | 2009 | Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model | 本標準已改版，請參考新版本標準。(ASTM F2761-09(2013)) |
| 172 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01073 | ISO | ISO/IEEE 11073-10201:2004 | 2004 | ISO/IEEE Health Informatics - Point-Of-Care Medical Device Communication - Part 10201: Domain Information Model | 本標準已改版，請參考新版本標準。(ISO/IEEE 11073-10201:2020) |
| 173 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01080 | ISO | ISO/IEEE 11073-10418:2014 | 2014 | Health informatics—Personal health device communication—Part 10418 Device specialization—International normalized ratio (INR) monitor | 本標準已改版，請參考新版本標準。(ISO/IEEE 11073-10418:2014/COR 1:2016) |

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| 174 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01663 | AAMI | AAMI TIR57:2016 | 2016 | Principles for medical device security—Risk management | 本標準已改版，請參考新版本標準。(AAMI TIR57:2016/(R)2019) |
| 175 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01853 | IEEE | IEEE 11073-10424:2016 | 2016 | Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE) | 本標準已改版，請參考新版本標準。(IEEE Std 11073-10424-2014/Cor 1-2017 ) |
| 176 | 14 Radiology 放射學科學 | TFDA-00279 | ISO | ISO 11551:2003 | 2003 | Optics and optical instruments - Lasers and laser-related equipment - Test method for absorptance of optical laser components | 本標準已改版，請參考新版本標準。(ISO 11551:2019) |
| 177 | 14 Radiology 放射學科學 | TFDA-00281 | ISO | ISO 11670:2003 | 2003 | Lasers and laser-related equipment - Test methods for laser beam parameters - Beam positional stability | 本標準已改版，請參考新版本標準。(ISO 11670:2003/COR 1:2004) |
| 178 | 14 Radiology 放射學科學 | TFDA-00427 | IEC | IEC/TR 60825-5:2003 Ed. 2.0 | 2003 | Safety of laser products - Part 5: Manufacturer's checklist for IEC 60825-1 | 原採認標準已廢除 |
| 179 | 14 Radiology 放射學科學 | TFDA-01391 | CNS | CNS 15585 | 2013 | 醫電設備電性安全－X 射線診斷造影使用之游離腔及/或半導體偵檢器劑量計 (Medical electrical equipment − Dosimeter with ionization chambers and/or semi-conductor detectors as used in | 原採認標準已廢除 |

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| | | | | | | X-ray diagnostic imaging (IDT: IEC 61674:1997)) | |
| 180 | 14 Radiology 放射學科學 | TFDA-01411 | IEC | IEC 61223-2-6:2006 | 2006 | Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment - Edition 2.0 | 原採認標準已廢除，請參考取代標準。(IEC 61223-3-5:2019 ) |
| 181 | 14 Radiology 放射學科學 | TFDA-01680 | ASTM | ASTM D7866-14 | 2014 | Standard Specification for Radiation Attenuating Protective Gloves | 本標準已改版，請參考新版本標準。(ASTM D7866-14a) |
| 182 | 14 Radiology 放射學科學 | TFDA-01682 | CNS | CNS 14509-2-28 | 2014 | 醫電設備－ 第 2-28 部： 醫用診斷 X 射線管組件基本安全及必要性能之特殊要求(Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis) | 原採認標準已廢除 |
| 183 | 14 Radiology 放射學科學 | TFDA-01683 | NEMA | DICOM PS3.1 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview | 本標準已改版，請參考新版本標準。(DICOM PS3.1 2020c) |
| 184 | 14 Radiology 放射學科學 | TFDA-01684 | NEMA | DICOM PS3.10 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for | 本標準已改版，請參考新版本標準。(DICOM PS3.10 2020c) |

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| | | | | | | Media Interchange | |
| 185 | 14 Radiology 放射學科學 | TFDA-01685 | NEMA | DICOM PS3.11 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles | 本標準已改版，請參考新版本標準。(DICOM PS3.11 2020c) |
| 186 | 14 Radiology 放射學科學 | TFDA-01686 | NEMA | DICOM PS3.12 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange | 本標準已改版，請參考新版本標準。(DICOM PS3.12 2020c) |
| 187 | 14 Radiology 放射學科學 | TFDA-01687 | NEMA | DICOM PS3.14 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function | 本標準已改版，請參考新版本標準。(DICOM PS3.14 2020bc) |
| 188 | 14 Radiology 放射學科學 | TFDA-01688 | NEMA | DICOM PS3.15 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 15: Security and System Management Profiles | 本標準已改版，請參考新版本標準。(DICOM PS3.15 2020c) |
| 189 | 14 Radiology 放射學科學 | TFDA-01689 | NEMA | DICOM PS3.16 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource | 本標準已改版，請參考新版本標準。(DICOM PS3.16 2020c) |
| 190 | 14 Radiology 放射學科學 | TFDA-01690 | NEMA | DICOM PS3.17 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 17: Explanatory Information | 本標準已改版，請參考新版本標準。(DICOM PS3.17 2020c) |
| 191 | 14 Radiology 放射學科學 | TFDA-01691 | NEMA | DICOM PS3.18 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Access to DICOM Persistent Objects | 本標準已改版，請參考新版本標準。(DICOM PS3.18 2020c) |

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| | | | | | | (WADO) | |
| 192 | 14 Radiology 放射學科學 | TFDA-01692 | NEMA | DICOM PS3.19 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 19: Application Hosting | 本標準已改版，請參考新版本標準。(DICOM PS3.19 2020c) |
| 193 | 14 Radiology 放射學科學 | TFDA-01693 | NEMA | DICOM PS3.2 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 2: Conformance | 本標準已改版，請參考新版本標準。(DICOM PS3.2 2020c) |
| 194 | 14 Radiology 放射學科學 | TFDA-01694 | NEMA | DICOM PS3.20 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 20: Transformation of DICOM to and from HL7 Standards | 本標準已改版，請參考新版本標準。(DICOM PS3.20 2020c) |
| 195 | 14 Radiology 放射學科學 | TFDA-01695 | NEMA | DICOM PS3.3 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions | 本標準已改版，請參考新版本標準。(DICOM PS3.3 2020c) |
| 196 | 14 Radiology 放射學科學 | TFDA-01696 | NEMA | DICOM PS3.4 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications | 本標準已改版，請參考新版本標準。(DICOM PS3.4 2020c) |
| 197 | 14 Radiology 放射學科學 | TFDA-01697 | NEMA | DICOM PS3.5 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding | 本標準已改版，請參考新版本標準。(DICOM PS3.5 2020c) |
| 198 | 14 Radiology 放射學科學 | TFDA-01698 | NEMA | DICOM PS3.6 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 6: Data Dictionary | 本標準已改版，請參考新版本標準。(DICOM PS3.6 2020c) |
| 199 | 14 Radiology 放射學科 | TFDA-01699 | NEMA | DICOM PS3.7 2016e | 2016 | Digital Imaging and Communications | 本標準已改版，請參考新版 |

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| | 學 | | | | | in Medicine (DICOM) Part 7: Message Exchange | 本標準。(DICOM PS3.7 2020c) |
| 200 | 14 Radiology 放射學科學 | TFDA-01700 | NEMA | DICOM PS3.8 2016e | 2016 | Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange | 本標準已改版，請參考新版本標準。(DICOM PS3.8 2020c) |
| 201 | 14 Radiology 放射學科學 | TFDA-01705 | IEC | IEC 60601-2-26:2015 | 2015 | Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs | 原採認標準已廢除，請參考取代標準。(IEC 80601-2-26:2019 ) |
| 202 | 14 Radiology 放射學科學 | TFDA-01717 | IEC | IEC 61223-3-5:2004+Corr1: 2006 | 2006 | Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment - Edition 1.0 | 原採認標準已廢除 |
| 203 | 14 Radiology 放射學科學 | TFDA-01860 | IEC | IEC 60601-2-43:2017 | 2017 | Medical electrical equipment - Part 2-43:Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures | 本標準已改版，請參考新版本標準。(IEC 60601-2-43:2010+AMD1:2017+AMD2:2019 CSV ) |
| 204 | 15 Sterility 滅菌 | TFDA-00233 | CNS | CNS 14709 | 2013 | Sterilization of medical devices - Validation and routine control of | 原採認標準已廢除 |

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| | | | | | | sterilisation by irradiation (MOD ISO 11737) | |
| 205 | 15 Sterility 滅菌 | TFDA-00353 | ISO | ISO 14644-3:2005 | 2005 | Cleanrooms and associated controlled environments —Part 3: Test methods | 本標準已改版，請參考新版本標準。(ISO 14644-3:2019) |
| 206 | 15 Sterility 滅菌 | TFDA-00867 | AAMI | ST50:2004/(R)2010 | 2010 | Dry heat (heated air) sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST50:2004/(R)2018) |
| 207 | 15 Sterility 滅菌 | TFDA-00868 | ISO | ISO 11737-2:2009 | 2009 | Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process | 本標準已改版，請參考新版本標準。(ISO 11737-2:2019) |
| 208 | 15 Sterility 滅菌 | TFDA-01027 | AAMI | AAMI ST8:2013 | 2013 | Hospital steam sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST8 : 2013(R2018)) |
| 209 | 15 Sterility 滅菌 | TFDA-01028 | AAMI | AAMI ST24:1999/(R)2009 | 2009 | Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities | 本標準已改版，請參考新版本標準。(AAMI ST24:1999/(R)2018) |
| 210 | 15 Sterility 滅菌 | TFDA-01029 | AAMI | AAMI ST77:2013 | 2013 | Containment devices for reusable medical device sterilization, 2nd ed. | 本標準已改版，請參考新版本標準。(AAMI ST77:2013/(R)2018) |
| 211 | 15 Sterility 滅菌 | TFDA-01050 | ISO | ISO/ASTM 52628:2013 | 2013 | Practice for dosimetry in radiation processing | 本標準已改版，請參考新版本標準。(ISO/ASTM |

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| | | | | | | | 52628:2020) |
| 212 | 16 Tissue Engineering 組織工程 | TFDA-00741 | ASTM | ASTM F2311-08 | 2008 | Standard Guide for Classification of Therapeutic Skin Substitutes | 原採認標準已廢除 |
| 213 | 16 Tissue Engineering 組織工程 | TFDA-01104 | ASTM | ASTM F2451-05/(R)2010 | 2010 | Standard Guide for in vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage | 原採認標準已廢除 |
| 214 | 16 Tissue Engineering 組織工程 | TFDA-01106 | ASTM | ASTM F2212-11 | 2011 | Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs) | 本標準已改版，請參考新版本標準。(ASTM F2212 - 19) |
| 215 | 17 Neurology 神經學 | TFDA-00708 | ASTM | ASTM F647-94/(R)2006 | 2006 | Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application | 本標準已改版，請參考新版本標準。(ASTM F647 - 94(2014) ) |
| 216 | 17 Neurology 神經學 | TFDA-01321 | AAMI | AAMI NS28:1988/(R)2010 | 2010 | Intracranial Pressure Monitoring Devices | 本標準已改版，請參考新版本標準。(AAMI NS28:1988/(R)2015) |
| 217 | 17 Neurology 神經學 | TFDA-01750 | AAMI | AAMI NS4:2013 | 2013 | Transcutaneous electrical nerve stimulators | 本標準已改版，請參考新版本標準。(AAMI NS4:2013/(R)2017) |
| 218 | 17 Neurology 神經學 | TFDA-01751 | CNS | CNS 14509-2-10 | 2014 | 醫電設備－第 2-10 部：神經與肌肉刺激器基本安全及必要性能之特殊 | 原採認標準已廢除 |

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| | | | | | | 要求(Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators) | |
| 219 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01010 | IEC | IEC 60601-2-22:2012 | 2012 | Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment - Edition 3.1 | 原採認標準已廢除 |
| 220 | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01756 | IEC | IEC/TR 60601-4-1:2016 | 2016 | Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy | 本標準已改版，請參考新版本標準。(IEC/TR 60601-4-1:2017) |

**表二、104 年度至 108 年度已公告廢除/改版之醫療器材標準共 813 項。**

| 序號 | 標準類別 | TFDA 採認編號 | 標準組織名稱 | 標準號碼 | 標準版本 | 標準名稱 | 備註說明 |
|---|---|---|---|---|---|---|---|
| 1 | 1 Anesthesias 麻醉學 | TFDA-00405 | ISO | ISO 10524-1: 2006 | 2006-02-01 | Pressure regulators for use with medical gases – Part 1: Pressure regulators and pressure regulators with flow-metering devices | 本標準已改版，請參考新版本標準。(ISO 10524-1: 2018) |
| 2 | 1 Anesthesias 麻醉學 | TFDA-00406 | ISO | ISO 10524-2: 2005 | 2005-05-01 | Pressure regulators for use with medical gases – Part 2: Manifold and line pressure regulators | 本標準已改版，請參考新版本標準。(ISO 10524-2: 2018) |
| 3 | 1 Anesthesias 麻醉學 | TFDA-01161 | IEC | IEC 60601-2-49:2011 | 2011-02-25 | Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment - Edition 2.0 | 本標準已改版，請參考新版本標準。(IEC 80601-2-49:2018) |
| 4 | 1 Anesthesias 麻醉學 | TFDA-01176 | ISO | ISO 80601-2-55:2011 | 2011-12-15 | Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors | 本標準已改版，請參考新版本標準。(ISO 80601-2-55:2018) |
| 5 | 1 Anesthesias 麻醉學 | TFDA-01458 | ISO | ISO 5359:2014 | 2014 | Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases | 本標準已改版，請參考新版本標準。(ISO 5359:2014+A1:2107) |

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| 6 | 1 Anesthesias 麻醉學 | TFDA-01466 | ISO | ISO 80601-2-13:2011/ Amd1:2015 | 2015 | Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation | 本標準已改版，請參考新版本標準。(IEC 80601-2-13:2018) |
| 7 | 2 Biocompatibility 生物相容性 | TFDA-00515 | ISO | ISO 10993-4:2002/ Amd 1:2006 | 2006-07-15 | Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood | 本標準已改版，請參考新版本標準。(ISO 10993-4:2017) |
| 8 | 2 Biocompatibility 生物相容性 | TFDA-00518 | ISO | ISO 10993-11:2006 | 2006-08-15 | Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity | 本標準已改版，請參考新版本標準。(ISO 10993-11:2018) |
| 9 | 2 Biocompatibility 生物相容性 | TFDA-00861 | ISO | ISO 10993-16:2010 | 2010-2-15 | Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables | 本標準已改版，請參考新版本標準。(ISO 10993-16:2017) |
| 10 | 2 Biocompatibility 生物相容性 | TFDA-01020 | ASTM | ASTM F720-13 | 2013-07-01 | Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test | 本標準已改版，請參考新版本標準。(ASTM F720:2017) |
| 11 | 2 Biocompatibility 生物相容性 | TFDA-01470 | ASTM | ASTM F2382-04/(R)2010 | 2010 | Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT) | 本標準已改版，請參考新版本標準。(ASTM F2382-17) |
| 12 | 3 Cardiovascular 心臟血管醫學 | TFDA-01204 | IEC | IEC 60601-2-4:2010 ed3.0 | 2010-12-08 | Medical electrical equipment - Part 2-4: Particular requirements for the | 本標準已改版，請參考新版本標準。(IEC 60601-2-4:2018) |

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| | | | | | | basic safety and essential performance of cardiac defibrillators | |
| 13 | 3 Cardiovascular 心臟血管醫學 | TFDA-01206 | IEC | IEC 80601-2-30:2013 | 2013-07-31 | Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers - Edition 1.1 | 本標準已改版，請參考新版本標準。(IEC 80601-2-30:2018) |
| 14 | 3 Cardiovascular 心臟血管醫學 | TFDA-01207 | IEC | IEC 80601-2-61:2012 | 2011-03-16 | Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment - Edition 1.0 | 本標準已改版，請參考新版本標準。(ISO/IEC 80601-2-61:2017) |
| 15 | 3 Cardiovascular 心臟血管醫學 | TFDA-01217 | ISO | ISO 80601-2-61:2011 | 2011-04-01 | Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment | 本標準已改版，請參考新版本標準。(ISO 80601-2-61:2017) |
| 16 | 3 Cardiovascular 心臟血管醫學 | TFDA-01477 | ASTM | ASTM F2004-16 | 2016 | Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis | 本標準已改版，請參考新版本標準。(ASTM F2004-17) |
| 17 | 3 Cardiovascular 心臟血管醫學 | TFDA-01479 | ASTM | ASTM F2129-15 | 2015 | Standard Test Method for Conducting Cyclic Potentiodynamic | 本標準已改版，請參考新版本標準。(ASTM F2129-17) |

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| | | | | | | Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices | |
| 18 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00684 | ISO | ISO 10139-1:2005 & ISO 10139-1:2005/Cor 1:2006 | 2006-3-1 | Dentistry - Soft lining materials for removable dentures - Part 1: Materials for short-term use Technical Corrigendum 1:2006. | 本標準已改版，請參考新版本標準。(ISO 10139-1: 2018) |
| 19 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00685 | ISO | ISO 10477:2004 | 2004-10-1 | Dentistry -- Polymer-based crown and bridge materials | 本標準已改版，請參考新版本標準。(ISO 10477:2018) |
| 20 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00871 | ISO | ISO 22112:2005 | 2005-11-1 | Dentistry -- Artificial teeth for dental prostheses | 本標準已改版，請參考新版本標準。(ISO 22112:2107) |
| 21 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00875 | ISO | ISO 9917-2:2010 | 2010-4-15 | Dentistry -- Water-based cements -- Part 2: Resin-modified cements | 本標準已改版，請參考新版本標準。(ISO 9917-2:2017) |
| 22 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01230 | ISO | ISO 14457:2012 | 2012-09-15 | Dentistry -- Handpieces and motors | 本標準已改版，請參考新版本標準。(ISO 14457:2017) |
| 23 | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01237 | ISO | ISO 7494-1:2011 | 2011-08-15 | Dentistry -- Dental units -- Part 1: General requirements and test methods | 本標準已改版，請參考新版本標準。(ISO 7494-1:2018) |
| 24 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-00120 | ISO | ISO 7886-1:1993 | 1995-11-01 | Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use | 本標準已改版，請參考新版本標準。(ISO 7886-1:2017) |

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| | 個人使用裝置 | | | | | | |
| 25 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00641 | ISO | ISO 7886-2:1996 | 1996-05-15 | Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps | 重覆採認標準 |
| 26 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00931 | ASTM | ASTM F1670-08 | 2008-9 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood | 本標準已改版，請參考新版本標準。(ASTM F1670/F1670M:2017) |
| 27 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01254 | IEC | IEC 80601-2-59:2008 | 2008-10-21 | Medical electrical equipment -- Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening | 本標準已改版，請參考新版本標準。(IEC 80601-2-59:2017) |
| 28 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01273 | ASTM | ASTM F1978-12 | 2012-06-01 | Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser | 本標準已改版，請參考新版本標準。(ASTM F1978:2018) |

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| 29 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01300 | ISO | ISO 10555-1:2013 | 2013-06-15 | Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements | 本標準已改版，請參考新版本標準。(ISO 10555-1:2013 + A1:2017) |
| 30 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01304 | ISO | ISO 11608-1:2014 | 2012-04-01 | Needle-based injection systems for medical use -- Requirements and test methods -- Part 1: Needle-based injection systems | 本標準已改版，請參考新版本標準。(ISO 11608-1:2015) |
| 31 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01524 | ASTM | ASTM F2052-14 | 2014 | Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment | 本標準已改版，請參考新版本標準。(ASTM F2052-15) |
| 32 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01526 | ASTM | ASTM F703-07 | 2007 | Standard Specification for Implantable Breast Prostheses | 本標準已改版，請參考新版本標準。(ASTM F703-18) |
| 33 | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-01533 | IEC | IEC 60601-2-19+A11:2011 | 2011 | Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators | 本標準已改版，請參考新版本標準。(IEC 60601-2-19:2016) |

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| | 個人使用裝置 | | | | | | |
| 34 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00224 | CLSI | T/DM6-A | 1997-09 | Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997) | 本標準已廢止 |
| 35 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00484 | CNS | CNS 15035:2006 | 1996-10-31 | 體外診斷系統－糖尿病管理時自我檢測用血糖監測系統之規定 | 本標準已廢止 |
| 36 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00503 | CLSI | M22-A3 | 2004-06-20 | Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition | 重覆採認標準 |
| 37 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00648 | CLSI | M6-A2 | 2006-1-20 | Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard - Second Edition | 本標準已廢止 |
| 38 | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00656 | CLSI | ILA2-A2 | 2006-3-22 | Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods; Approved Guideline - Second Edition | 本標準已廢止 |
| 39 | 8 Materials 材料 | TFDA-00067 | ISO | ISO 5832-2:1999 | 1999-07-15 | Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium | 本標準已改版，請參考新版本標準。(ISO 5832-2:2018) |

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| 40 | 8 Materials 材料 | TFDA-01085 | AATCC | AATCC 127-2008 | 2014-01-01 | Water Resistance: Hydrostatic Pressure Test | 本標準已改版，請參考新版本標準。(AATCC 127-2017) |
| 41 | 8 Materials 材料 | TFDA-01095 | ASTM | ASTM F2459-12 | 2012-03-01 | Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis | 本標準已改版，請參考新版本標準。(ASTM F2459:2018) |
| 42 | 8 Materials 材料 | TFDA-01580 | AATCC | AATCC 128-2013 | 2013 | Water Resistance: Hydrostatic Pressure Test | 本標準已改版，請參考新版本標準。(AATCC 128:2017) |
| 43 | 8 Materials 材料 | TFDA-01582 | ASTM | ASTM D412-15 | 2015 | Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension | 本標準已改版，請參考新版本標準。(ASTM D412-16) |
| 44 | 8 Materials 材料 | TFDA-01586 | ASTM | ASTM F1925-09 | 2009 | Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants | 本標準已改版，請參考新版本標準。(ASTM F1925-17) |
| 45 | 8 Materials 材料 | TFDA-01587 | ASTM | ASTM F2026-2016 | 2016 | Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications | 本標準已改版，請參考新版本標準。(ASTM F2026-17) |
| 46 | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01253 | IEC | IEC 60601-2-16:2012 | 2012-03-01 | Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and | 本標準已改版，請參考新版本標準。(IEC 60601-2-16:2018) |

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| | | | | | | haemofiltration equipment. | |
| 47 | 10 Ophthalmic 眼科學 | TFDA-00722 | ISO | ISO 18369-3:2006 | 2006-8-15 | Ophthalmic optics -- Contact lenses -- Part 3: Measurement methods | 本標準已改版，請參考新版本標準。(ISO 18369-3:2017) |
| 48 | 10 Ophthalmic 眼科學 | TFDA-00723 | ISO | ISO 18369-4:2006 | 2006-8-15 | Ophthalmic optics -- Contact lenses -- Part 4: Physicochemical properties of contact lens materials | 本標準已改版，請參考新版本標準。(ISO 18369-4:2017) |
| 49 | 10 Ophthalmic 眼科學 | TFDA-00724 | ISO | ISO 18369-1:2006/Amd 1:2009 | 2009-2-15 | Ophthalmic optics -- Contact lenses -- Part 1: Vocabulary, classification system and recommendations for labelling specifications | 本標準已改版，請參考新版本標準。(ISO 18369-1:2017) |
| 50 | 10 Ophthalmic 眼科學 | TFDA-00934 | ISO | ISO 11981:2009 | 2009-7-1 | Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of physical compatibility of contact lens care products with contact lenses | 本標準已改版，請參考新版本標準。(ISO 11981:2017) |
| 51 | 10 Ophthalmic 眼科學 | TFDA-00992 | ISO | ISO 8980-1:2004/Cor 1:2006 | 1996-02-01; technical corrigendum 1:2006-08-01 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 1: Specifications for single-vision and multifocal lenses | 本標準已改版，請參考新版本標準。(ISO 8980-1:2017) |
| 52 | 10 Ophthalmic 眼科學 | TFDA-00993 | ISO | ISO 8980-2:2004/Cor 1:2006 | 2004-02-01; technical corrigendum | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 2: Specifications for progressive power | 本標準已改版，請參考新版本標準。(ISO 8980-1:2017) |

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| | | | | | 1:2006-08-01 | lenses | |
| 53 | 10 Ophthalmic 眼科學 | TFDA-01330 | ISO | ISO 10936-1:2000 | 2000-06-15 | Optics and optical instruments -- Operation microscopes -- Part 1: Requirements and test methods | 本標準已改版，請參考新版本標準。(ISO 10936-1:2017) |
| 54 | 10 Ophthalmic 眼科學 | TFDA-01337 | ISO | ISO 11979-7:2014 | 2014-09-01 | Ophthalmic Implants - Intraocular Lenses - Part 7: Clinical Investigations - Third Edition | 本標準已改版，請參考新版本標準。(ISO 11979-7:2018) |
| 55 | 10 Ophthalmic 眼科學 | TFDA-01338 | ISO | ISO 11979-8/Amd 1:2011 | 2011-05-15 | Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements AMENDMENT 1 - Second Edition | 本標準已改版，請參考新版本標準。(ISO 11979-8:2018) |
| 56 | 10 Ophthalmic 眼科學 | TFDA-01340 | ISO | ISO 11986:2010 | 2010-10-01 | Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of preservative uptake and release | 本標準已改版，請參考新版本標準。(ISO 11986:2017) |
| 57 | 10 Ophthalmic 眼科學 | TFDA-01343 | ISO | ISO 18369-2:2012 | 2012-12-01 | Ophthalmic optics -- Contact lenses -- Part 2: Tolerances | 本標準已改版，請參考新版本標準。(ISO 18369-2:2017) |
| 58 | 10 Ophthalmic 眼科學 | TFDA-01613 | IEC | IEC 80601-2-58:2014 | 2014 | Medical electrical equipment -- Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery | 本標準已改版，請參考新版本標準。(IEC 80601-2-58:2016) |

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| 59 | 10 Ophthalmic 眼科學 | TFDA-01614 | ISO | ISO 11979-10/Amd1:2014 | 2014 | Ophthalmic implants Intraocular lenses Part 10: Phakic intraocular lenses | 本標準已改版，請參考新版本標準。(ISO 11979-10:2018) |
| 60 | 11 Orthopaedics 骨科學 | TFDA-01349 | ASTM | ASTM D732-10 | 2010-04-01 | Standard Test Method for Shear Strength of Plastics by Punch Tool | 本標準已改版，請參考新版本標準。(ASTM D732:2017) |
| 61 | 11 Orthopaedics 骨科學 | TFDA-01351 | ASTM | ASTM E399-12 | 1905-07-04 | Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness KIc of Metallic Materials | 本標準已改版，請參考新版本標準。(ASTM E399:2017) |
| 62 | 11 Orthopaedics 骨科學 | TFDA-01352 | ASTM | ASTM F1541-02/(R)2011 | 2011-10-01 | Standard Specification and Test Methods for External Skeletal Fixation Devices | 本標準已改版，請參考新版本標準。(ASTM F1541:2017) |
| 63 | 11 Orthopaedics 骨科學 | TFDA-01367 | ASTM | ASTM F1378–12 | 2012-01-01 | Standard Specification for Shoulder Prostheses | 本標準已改版，請參考新版本標準。(ASTM F1378:2017) |
| 64 | 11 Orthopaedics 骨科學 | TFDA-01372 | ASTM | ASTM F2028-14 | 2014-03-01 | Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation | 本標準已改版，請參考新版本標準。(ASTM F2028:2017) |
| 65 | 11 Orthopaedics 骨科學 | TFDA-01377 | ASTM | ASTM F2502-11 | 2011-06-01 | Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants. | 本標準已改版，請參考新版本標準。(ASTMF2502-:2017) |
| 66 | 11 Orthopaedics 骨科學 | TFDA-01622 | ASTM | ASTM F1717-14 | 2014 | Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model | 本標準已改版，請參考新版本標準。(ASTM F1717-15) |

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| 67 | 11 Orthopaedics 骨科學 | TFDA-01623 | ASTM | ASTM F1829-16 | 2016 | Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear | 本標準已改版，請參考新版本標準。(ASTM F1829-17) |
| 68 | 11 Orthopaedics 骨科學 | TFDA-01624 | ASTM | ASTM F2077-14 | 2014 | Test Methods For Intervertebral Body Fusion Devices | 本標準已改版，請參考新版本標準。(ASTM F2077-17) |
| 69 | 12 Physical Medicine 物理醫學科學 | TFDA-00152 | ISO | ISO 7176-2:2001 | 2001-06-15 | Wheelchairs - Part 2: Determination of Dynamic Stability of Electric Wheelchairs | 本標準已改版，請參考新版本標準。(ISO 7176-2:2017) |
| 70 | 12 Physical Medicine 物理醫學科學 | TFDA-00156 | ISO | ISO 7176-6:2001 | 2001-10-01 | Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs | 本標準已改版，請參考新版本標準。(ISO 7176-6:2018) |
| 71 | 12 Physical Medicine 物理醫學科學 | TFDA-01657 | IEC | IEC 60601-2-3:2015 | 2015 | Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of shortwave therapy equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-3:2016) |
| 72 | 12 Physical Medicine 物理醫學科學 | TFDA-01658 | IEC | IEC 60601-2-6:2015 | 2015 | Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-6:2016) |
| 73 | 12 Physical Medicine 物理醫學科學 | TFDA-01660 | ISO | ISO 7176-19:2008 | 2008 | Wheelchairs Part 19: Wheeled mobility devices for use as seats in motor vehicles | 本標準已改版，請參考新版本標準。(ISO 7176-19:2015+A1:2015) |

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| 74 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00443 | AAMI | AAMI TIR32:2004 | 2004-12-23 | Medical device software risk management | 本標準已改版，請參考新版本標準。(AAMI/IEC TIR 80002-1:2009) |
| 75 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00488 | CLSI | AUTO1-A | 2000-12-20 | Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard | 本標準已廢止 |
| 76 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00645 | CLSI | AUTO9-A | 2006-3-22 | Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard | 本標準已改版，請參考新版本標準。(AUTO10-A) |
| 77 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00900 | ISO | ISO/IEC 12207:2008 ed2.0 | 2008-3-18 | Systems and software engineering -- Software life cycle processes | 本標準已改版，請參考新版本標準。(IEEE/IEC/ISO 12207:2017) |
| 78 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01066 | IEC | IEC/TR 80002-3:2014 ed1.0 | 2014-06-01 | Medical device software –Part 3: Process reference model of medical device software life cycle processes (IEC 62304) | 重覆採認標準 |
| 79 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01068 | IEEE | IEEE 1012:2012 | 2012-05-25 | IEEE Standard for System and Software Verification and Validation | 本標準已改版，請參考新版本標準。(IEEE 1012:2016) |
| 80 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01079 | ISO | ISO/IEEE 11073-10417:2014 | 2012-01-27 | Health informatics--Personal health device communication Part 10417: Device specialization--Glucose meter | 本標準已改版，請參考新版本標準。(ISO/IEEE 11073-10417:2017) |

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| 81 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01081 | ISO | ISO/IEEE 11073-10421:2012 | 2010-11-19 | Health informatics--Personal health device communication Part 10421: Device specialization--Peak expiratory flow monitor (peak flow) | 重覆採認標準 |
| 82 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01671 | IEEE | IEEE Std 11073-10425-2014 | 2014 | Health informatics—Personal health device communication Part 10425: Device Specialization—Continuous Glucose Monitor (CGM) | 本標準已改版，請參考新版本標準。(IEEE 11073-10425:2017) |
| 83 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01672 | IEEE | IEEE std 11073-20601-2014 | 2014 | IEEE Health informatics--Personal health device communication Part 20601: Application profile-Optimized Exchange Protocol. | 本標準已改版，請參考新版本標準。(IEEE 11073-20601:2016) |
| 84 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01673 | IEEE | IEEE Std 2010-2012 | 2012 | IEEE Recommended Practice for Neurofeedback Systems | 本標準已改版，請參考新版本標準。(IEEE 11073-20601:2016) |
| 85 | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01678 | ISO | ISO/IEEE 11073-10419:2016 | 2016 | Health informatics - Personal health device communication - Part 10419: Device Specialization - Insulin Pump | 本標準已改版，請參考新版本標準。(ISO/IEEE 11073-10102:2014) |
| 86 | 14 Radiology 放射學科學 | TFDA-00586 | ISO | ISO 12052:2006 | 2006-10-20 | Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management | 本標準已改版，請參考新版本標準。(ISO 12052:2017) |

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| 87 | 14 Radiology 放射學科學 | TFDA-00703 | ISO | ISO 11554:2006 | 2006-5-1 | Optics and photonics -- Lasers and laser-related equipment -- Test methods for laser beam power, energy and temporal characteristics | 本標準已改版，請參考新版本標準。(ISO 11554:2017) |
| 88 | 14 Radiology 放射學科學 | TFDA-00892 | IEC | IEC 60601-2-28:2010 ed2.0 | 2010-3-10 | Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis | 本標準已改版，請參考新版本標準。(IEC 60601-2-28:2017) |
| 89 | 14 Radiology 放射學科學 | TFDA-00893 | IEC | IEC 60601-2-43:2010 ed2.0 | 2010-3-25 | Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures | 本標準已改版，請參考新版本標準。(IEC 60601-2-43:2107) |
| 90 | 14 Radiology 放射學科學 | TFDA-01401 | IEC | IEC 60601-2-63 ed1.0 | 2012-09-01 | Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment - Edition 1.0 | 本標準已改版，請參考新版本標準。(IEC 60601-2-63:2017) |
| 91 | 14 Radiology 放射學科學 | TFDA-01402 | IEC | IEC 60601-2-65:2012 ed1.0 | 2012-09-01 | Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment - Edition 1.0 | 本標準已改版，請參考新版本標準。(IEC 60601-2-65:2017) |

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| 92 | 14 Radiology 放射學科學 | TFDA-01425 | IEC | IEC/TS 62462:2007 ed1.0 | 2007-05-01 | Ultrasonics—Output test—Guide for the maintenance of ultrasound physiotherapy systems. | 本標準已改版，請參考新版本標準。(IEC 62462:2017) |
| 93 | 15 Sterility 滅菌 | TFDA-00029 | ISO | ISO 13408-2:2003 | 2003-03-15 | Aseptic Processing of Health Care Products - Part 2: Filtration | 本標準已改版，請參考新版本標準。(ISO 13408-2:2018) |
| 94 | 15 Sterility 滅菌 | TFDA-00358 | ISO | ISO 11137-3:2006 | 2006-03-12 | Sterilization of health care products —Radiation —Part 3: Guidance on dosimetric aspects | 本標準已改版，請參考新版本標準。(ISO 11137-3:2018) |
| 95 | 15 Sterility 滅菌 | TFDA-00527 | ISO | ISO 11737-1:2006 | 2006-03-20 | Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products | 本標準已改版，請參考新版本標準。(ISO 11737-1:2018) |
| 96 | 15 Sterility 滅菌 | TFDA-01026 | AAMI | AAMI ST55:2010 | 2010-01-01 | Table-Top Steam Sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST55:2016) |
| 97 | 16 Tissue Engineering 組織工程 | TFDA-01746 | ASTM | ASTM F2064-14 | 2014 | Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Products Application | 本標準已改版，請參考新版本標準。(ASTM F2064-17) |
| 98 | 16 Tissue Engineering 組織工程 | TFDA-01747 | ISO | ISO 22442-1:2015 | 2015 | Medical devices utilizing animal tissues and their derivatives Part 1: Application of risk management | 本標準已改版，請參考新版本標準。(ASTM F2064-17) |

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| 99. | 1 Anesthesias 麻醉學 | TFDA-00093 | IEC | IEC 60601-3-1:1996 | 1996-07 | Medical Electrical Equipment Part 3-1: Essential Performance Requirements for Transcutaneous Oxygen and Carbon Dioxide Partial Pressure Monitoring Equipment | 本標準已廢除，無取代標準。 |
| 100. | 1 Anesthesias 麻醉學 | TFDA-00094 | ISO | ISO 5360:1993 | 1998-12-01 | Anaesthetic vaporizers - Agent specific filling systems | 本標準已改版，請參考新版本標準。(ISO 5360:2016) |
| 101. | 1 Anesthesias 麻醉學 | TFDA-00095 | ISO | ISO 5361:1999 | 1999-09-15 | Anaesthetic and Respiratory Equipment - Tracheal Tubes and Connectors | 本標準已改版，請參考新版本標準。(ISO 5361:2016) |
| 102. | 1 Anesthesias 麻醉學 | TFDA-00096 | ISO | ISO 5361-4:1987 | 1987-12-15 | Tracheal Tubes - Part 4: Cole Type | 本標準已改版，請參考新版本標準。(ISO 5361:2016) |
| 103. | 1 Anesthesias 麻醉學 | TFDA-00097 | ISO | ISO 5362:2000 | 2000-12-01 | Anaesthetic Reservoir Bags | 本標準已改版，請參考新版本標準。(ISO 5362:2006) |
| 104. | 1 Anesthesias 麻醉學 | TFDA-00098 | ISO | ISO 5366-1:2000 | 2000/12/15 | Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults | 本標準已改版，請參考新版本標準。(ISO 5366:2016) |
| 105. | 1 Anesthesias 麻醉學 | TFDA-00099 | ISO | ISO 5366-3:2001 | 2003/01/15 | Anaesthetic and Respiratory Equipment -- Tracheostomy Tubes -- Part 3: Pediatric Tracheostomy Tubes | 本標準已改版，請參考新版本標準。(ISO 5366:2016) |
| 106. | 1 Anesthesias 麻醉學 | TFDA-00100 | ISO | ISO 5367:2000 | 2000/06/01 | Breathing Tubes intended for use with Anaesthetic Apparatus and | 本標準已改版，請參考新版本標準。(ISO 5367:2014) |

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| | | | | | | Ventilators | |
| 107. | 1 Anesthesias 麻醉學 | TFDA-00101 | ISO | ISO 7767:1997 | 1997-05-01 | Oxygen Monitors for Monitoring Patient Breathing Mixtures - Safety Requirements | 本標準已廢除，請參考新標準。(ISO 80601-2-55:2011) |
| 108. | 1 Anesthesias 麻醉學 | TFDA-00102 | ISO | ISO 8359:1996 | 1996-12-15 | Oxygen Concentrators for Medical Use - Safety Requirements | 本標準已改版，請參考新版本標準。(ISO 8359:1996/Amd 1:2012) |
| 109. | 1 Anesthesias 麻醉學 | TFDA-00103 | ISO | ISO 8382:1988 | 1988-12-15 | Resuscitators Intended for Use with Humans | 本標準已廢除，請參考新標準。(ISO 10651-5: 2006) |
| 110. | 1 Anesthesias 麻醉學 | TFDA-00104 | ISO | ISO 9918:1993 | 1993-02-15 | Capnometers for Use with Humans - Requirements | 本標準已廢除，請參考新標準。(ISO 80601-2-55:2011) |
| 111. | 1 Anesthesias 麻醉學 | TFDA-00262 | ASTM | ASTM F1850-00 | 2000-03 | Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components1 | 本標準已改版，請參考新版本標準。(ASTM F1850-00/(R)2005) |
| 112. | 1 Anesthesias 麻醉學 | TFDA-00265 | ASTM | ASTM F920-93(R1999) | 1993-05 | Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans | 本標準已廢除，請參考新標準。(ISO 10651-4: 2002) |
| 113. | 1 Anesthesias 麻醉學 | TFDA-00266 | ASTM | ASTM F1100-90(R1997) | 1990-06 | Standard Specification for Ventilators Intended for Use in Critical Care | 本標準已廢除，請參考新版本標準。(ISO 80601-2-12:2011/Cor 1:2011) |

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| 114. | 1 Anesthesias 麻醉學 | TFDA-00269 | ASTM | ASTM F1101-90(R2003)e1 | 2003-12 | Standard Specification for Ventilators Intended for Use During Anesthesia | 本標準已廢除，請參考新標準。(ISO 80601-2-12: 2011/Cor 1:2011) |
| 115. | 1 Anesthesias 麻醉學 | TFDA-00270 | ASTM | ASTM G175-03 | 2003-05 | Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications | 本標準已改版，請參考新版本標準。(ASTM G175-13) |
| 116. | 1 Anesthesias 麻醉學 | TFDA-00271 | ASTM | ASTM F1456-01 | 2001-12 | Standard Specification for Minimum Performance and Safety Requirements for Capnometers | 本標準已廢除，請參考新標準。(ISO 80601-2-55:2011) |
| 117. | 1 Anesthesias 麻醉學 | TFDA-00407 | ISO | ISO 10524-3: 2005 | 2005-05-01 | Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves | 本標準已改版，請參考新版本標準。(ISO 10524-3:2005/Amd 1:2013) |
| 118. | 1 Anesthesias 麻醉學 | TFDA-00411 | ISO | ISO 21647: 2004/Cor 1:2005 | 2005-07-15 | Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors-Technical Corrigendum 1 | 本標準已廢除，請參考新標準。(ISO 80601-2-55:2011) |
| 119. | 1 Anesthesias 麻醉學 | TFDA-00445 | ISO | ISO 18779:2005 | 2005/02/15 | Medical devices for conserving oxygen and oxygen mixtures - Particular requirements | 本標準已被廢除，請參考新標準。(ISO 80601-2-67:2014) |

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| 120. | 1 Anesthesias 麻醉學 | TFDA-00694 | ISO | ISO 5360:2006 | 2006-10-1 | Anaesthetic vaporizers -- Agent-specific filling systems | 本標準已改版，請參考新版本標準。(ISO 5360:2016) |
| 121. | 1 Anesthesias 麻醉學 | TFDA-01154 | ASTM | ASTM G175 - 03(R2011) | 2011-4-1 | ASTM G175 - 03(2011) Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications | 本標準已改版，請參考新版本標準。(ASTM G175-13) |
| 122. | 1 Anesthesias 麻醉學 | TFDA-01160 | IEC | IEC 60601-2-13:2009 | 2009-8-31 | Medical electrical equipment – Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems - Edition 3.1; Consolidated Reprint | 本標準已被廢除，請參考新標準。(ISO 80601-2-13:2011 + AMD 1:2015) |
| 123. | 1 Anesthesias 麻醉學 | TFDA-01162 | ISO | ISO 10079-1:1999 | 1999-8-15 | Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements | 本標準已改版，請參考新版本標準。(ISO 10079-1:2015) |
| 124. | 1 Anesthesias 麻醉學 | TFDA-01163 | ISO | ISO 10079-2:1999 | 1999-8-15 | Medical suction equipment - Part 2: Manually powered suction equipment | 本標準已改版，請參考新版本標準。(ISO 10079-2:2014) |
| 125. | 1 Anesthesias 麻醉學 | TFDA-01164 | ISO | ISO 10079-3:1999 | 1999-8-15 | Medical suction equipment Part 3: Suction equipment powered from a vacuum or pressure source | 本標準已改版，請參考新版本標準。(ISO 10079-3:2014) |
| 126. | 1 Anesthesias 麻醉學 | TFDA-01166 | ISO | ISO 14408:2005 | 2005-6-1 | Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information | 本標準已改版，請參考新版本標準。(ISO 14408:2016) |

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| 127. | 1 Anesthesias 麻醉學 | TFDA-01169 | ISO | ISO 23747:2007 | 2007-7-15 | Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans | 本標準已改版，請參考新版本標準。(ISO 23747:2015) |
| 128. | 1 Anesthesias 麻醉學 | TFDA-01171 | ISO | ISO 5360:2012 | 2012-1-15 | Anaesthetic vaporizers -- Agent-specific filling systems | 本標準已改版，請參考新版本標準。(ISO 5360:2016) |
| 129. | 1 Anesthesias 麻醉學 | TFDA-01172 | ISO | ISO 5361:2012 | 2012-10-1 | Anaesthetic and respiratory equipment -- Tracheal tubes and connectors | 本標準已改版，請參考新版本標準。(ISO 5361:2016) |
| 130. | 1 Anesthesias 麻醉學 | TFDA-01177 | ISO | ISO 8359:1996/Amd 1:2012 | 2012-7-1 | Oxygen Concentrators for Medical Use - Safety Requirements | 本標準已被廢除，請參考新標準。(ISO 80601-2-69:2014) |
| 131. | 2 Biocompatibility 生物相容性 | TFDA-00006 | ISO | ISO 10993-1：2003 | 2003-08-15 | Biological evaluation of medical devices -- Part 1: Evaluation and testing. | 本標準已改版，請參考新版本標準。(ISO 10993-1:2009/Cor1:2010) |
| 132. | 2 Biocompatibility 生物相容性 | TFDA-00007 | ISO | ISO 10993-10：2002 | 2002-09-01 | Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization -- Maximization sensitization test. | 本標準已改版，請參考新版本標準。(ISO 10993-10:2010 ) |
| 133. | 2 Biocompatibility 生物相容性 | TFDA-00008 | ISO | ISO 10993-11：1993 | 1993-l 2-l 5 | Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity. | 本標準已改版，請參考新版本標準。(ISO 10993-11:2006) |

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| 134. | 2 Biocompatibility 生物相容性 | TFDA-00009 | ISO | ISO 10993-12：2002 | 2002-12-15 | Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials. | 本標準已改版，請參考新版本標準。(ISO 10993-12:2012) |
| 135. | 2 Biocompatibility 生物相容性 | TFDA-00010 | ISO | ISO 10993-5：1999 | 1999-05-15 | Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. | 本標準已改版，請參考新版本標準。(ISO 10993-5:2009 ) |
| 136. | 2 Biocompatibility 生物相容性 | TFDA-00011 | ISO | ISO 10993-6：1994 | 1994-07-l 5 | Biological evaluation of medical devices -- Part 6: Test for local effects after implantation. | 本標準已改版，請參考新版本標準。(ISO 10993-6:2016) |
| 137. | 2 Biocompatibility 生物相容性 | TFDA-00012 | ISO | ISO 10993-7：1995 | 1995-10-15 | Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. | 本標準已改版，請參考新版本標準。(ISO 10993-7:2008/Cor 1:2009) |
| 138. | 2 Biocompatibility 生物相容性 | TFDA-00016 | ISO | ISO 10993-2:1992 | 1992-12-15 | Biological evaluation of medical devices -- Part 2: Animal welfare requirements | 本標準已改版，請參考新版本標準。(ISO 10993-2:2006) |
| 139. | 2 Biocompatibility 生物相容性 | TFDA-00018 | ISO | ISO 10993-4:2002 | 2002-10-15 | Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood | 本標準已改版，請參考新版本標準。(ISO 10993-4:2002/Amd 1:2006) |
| 140. | 2 Biocompatibility 生物相容性 | TFDA-00019 | ISO | ISO 10993-9:1999 | 1999-03-01 | Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products | 本標準已改版，請參考新版本標準。(ISO 10993-9:2009) |
| 141. | 2 Biocompatibility 生物相容性 | TFDA-00020 | ISO | ISO 10993-13:1998 | 1998-11-15 | Biological evaluation of medical devices -- Part 13: Identification and | 本標準已改版，請參考新版本標準。(ISO |

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| 142. | 2 Biocompatibility 生物相容性 | TFDA-00023 | ISO | ISO 10993-16:1997 | 1997-09-01 | Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables | 本標準已改版，請參考新版本標準。(ISO 10993-16:2010 ) |
| 143. | 2 Biocompatibility 生物相容性 | TFDA-00514 | ISO | ISO 10993-3:2003 | 2003/10/15 | Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity | 本標準已改版，請參考新版本標準。(ISO 10993-3:2014) |
| 144. | 2 Biocompatibility 生物相容性 | TFDA-00516 | ISO | ISO 10993-6:2007 | 2007/04/04 | Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation | 本標準已改版，請參考新版本標準。(ISO 10993-6:2016) |
| 145. | 2 Biocompatibility 生物相容性 | TFDA-00517 | ISO | ISO 10993-10:2002/Amd 1:2006 | 2006-07-15 | Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity | 本標準已改版，請參考新版本標準。(ISO 10993-10:2010 ) |
| 146. | 2 Biocompatibility 生物相容性 | TFDA-00533 | ISO | ISO/TS 20993:2006 | 2006-07-26 | Biological evaluation of medical devices -- Guidance on a risk-management process | 本標準已廢除，請參考新標準。(ISO 10993-1:2009/Cor1:2010) |
| 147. | 2 Biocompatibility 生物相容性 | TFDA-00668 | ISO | ISO 10993-12:2007 | 2008-2-15 | Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials | 本標準已改版，請參考新版本標準。(ISO 10993-12:2012) |
| 148. | 2 Biocompatibility 生物相容性 | TFDA-00726 | ISO | ISO 10993-7：2008 | 2008-10-25 | Biological evaluation of medical devices -- Part 7: Ethylene oxide | 本標準已改版，請參考新版本標準。(ISO |

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| 149. | 3 Cardiovascular 心臟血管醫學 | TFDA-00313 | IEC | IEC 60601-2-31:1994 | 1998-01 | Medical electrical equipment, Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source | 本標準已改版，請參考新版本標準。(IEC 60601-2-31:2011 ed2.1 Consol. with am1) |
| 150. | 3 Cardiovascular 心臟血管醫學 | TFDA-00315 | IEC | IEC 60601-2-25 | 1999-05 | Medical Electrical Equipment-Part 2, Particular Requirements for the Safety of Electrocardiographs | 本標準已改版，請參考新版本標準。(IEC 60601-2-25:2011) |
| 151. | 3 Cardiovascular 心臟血管醫學 | TFDA-00316 | IEC | IEC 60601-2-47 | 2001-07 | Medical Electrical Equipment Part 2-47: Particular Requirements for the Safety, including Essential Performance of Ambulatory Electrocardiographic Systems | 本標準已改版，請參考新版本標準。(IEC 60601-2-47:2012 ed2.0) |
| 152. | 3 Cardiovascular 心臟血管醫學 | TFDA-00317 | IEC | IEC 60601-2-4 | 2002-08 | Particular Requirements for the Safety of Cardiac Defibrillator | 本標準已改版，請參考新版本標準。(IEC 60601-2-4:2010 ed3.0) |
| 153. | 3 Cardiovascular 心臟血管醫學 | TFDA-00446 | ISO | ISO 5840:2005 | 2005-03-07 | Cardiovascular implants - Cardiac valve prostheses | 本標準已改版，請參考新版本標準。(ISO 5840-1:2015) |
| 154. | 3 Cardiovascular 心臟血管醫學 | TFDA-00447 | ISO | ISO 14708-2: 2005 | 2005-10-01 | Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers | 本標準已改版，請參考新版本標準。(ISO 14708-2:2012) |

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| 155. | 3 Cardiovascular 心臟血管醫學 | TFDA-00448 | ISO | ISO 25539-1:2003/Amd 1:2005 | 2005/07/15 | Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses – Amendment 1: Test methods | 本標準已改版，請參考新版本標準。(ISO 25539-1:2017) |
| 156. | 3 Cardiovascular 心臟血管醫學 | TFDA-00449 | ISO | ISO 15676:2005 | 2005/07/15 | Cardiovascular implants and artificial organs – Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) | 本標準已改版，請參考新版本標準。(ISO 15676:2016membrane oxygenation (ECMO) - Second Edition) |
| 157. | 3 Cardiovascular 心臟血管醫學 | TFDA-00450 | ISO | ISO 7198:1998 | 1998/08/01 | Cardiovascular implants — Tubular vascular prostheses | 本標準已改版，請參考新版本標準。(ISO 7198:2017) |
| 158. | 3 Cardiovascular 心臟血管醫學 | TFDA-00451 | ISO | ISO 7199:1996 | 1996-12-15 | Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) | 本標準已改版，請參考新版本標準。(ISO 7199:2016) |
| 159. | 3 Cardiovascular 心臟血管醫學 | TFDA-00454 | ISO | ISO 15674:2001 | 2001-11-01 | Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags | 本標準已改版，請參考新版本標準。(ISO 15674:2016) |
| 160. | 3 Cardiovascular 心臟血管醫學 | TFDA-00455 | ISO | ISO 15675:2001 | 2001-10-01 | Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial line blood filters | 本標準已改版，請參考新版本標準。(ISO 15675:2016) |
| 161. | 3 Cardiovascular 心臟血管醫學 | TFDA-00456 | ISO | ISO 13960:2003 | 2003-12-01 | Cardiovascular implants and artificial organs – Plasmafilters | 本標準已改版，請參考新版本標準。(ISO 13960:2010 ) |

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| 162. | 3 Cardiovascular 心臟血管醫學 | TFDA-00474 | CEN | EN 14299:2004 | 2004-06-08 | Non active surgical implants - Particular requirements for cardiac and vascular implants - Specific requirements for arterial stents | 本標準已廢除，請參考新標準。(ISO 25539-1:2017) |
| 163. | 3 Cardiovascular 心臟血管醫學 | TFDA-00475 | CEN | EN 12006-1:1999 | 1999-11-15 | Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 1: Heart valve substitutes | 本標準已廢除，請參考新標準。(ISO 5840-1:2015) |
| 164. | 3 Cardiovascular 心臟血管醫學 | TFDA-00476 | CEN | EN 12006-2:1998 | 1998-07-15 | Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits | 本標準已改版，請參考新版本標準。(EN 12006-2:1998+A1:2009) |
| 165. | 3 Cardiovascular 心臟血管醫學 | TFDA-00477 | CEN | EN 12006-3:1998 | 1999-03-15 | Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices | 本標準已廢除，請參考新標準。(ISO 25539-1:2017) |
| 166. | 3 Cardiovascular 心臟血管醫學 | TFDA-00605 | ASTM | ASTM F2081-01 | 2001-04-01 | Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents | 本標準已改版，請參考新版本標準。(ASTM F2081-06/(R)2013) |
| 167. | 3 Cardiovascular 心臟血管醫學 | TFDA-00613 | AAMI | AAMI DF80:2003 | 2003-10-23 | Medical electrical equipment—Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external | 本標準已廢除，請參考新標準。(IEC 60601-2-4:2010 ed3.0) |

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| 168. | 3 Cardiovascular 心臟血管醫學 | TFDA-00614 | AAMI | AAMI EC11:1991(R2001) | 2001-05-04 | Diagnostic electrocardiographic devices | 本標準已廢除，請參考新標準。(IEC 60601-2-25: 2011) |
| 169. | 3 Cardiovascular 心臟血管醫學 | TFDA-00615 | AAMI | AAMI EC12:2000/(R)2005 | 2005-01-06 | Disposable ECG electrodes | 本標準已改版，請參考新版本標準。(AAMI EC12:2000/(R)2010 ) |
| 170. | 3 Cardiovascular 心臟血管醫學 | TFDA-00616 | AAMI | AAMI EC53:1995/(R)2001 | 2001-05-11 | ECG cables and leadwires | 本標準已改版，請參考新版本標準。(AAMI EC53:2013) |
| 171. | 3 Cardiovascular 心臟血管醫學 | TFDA-00617 | AAMI | AAMI EC57:1998/(R)2003 | 2003-12-18 | Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms | 本標準已改版，請參考新版本標準。(AAMI EC57:2012) |
| 172. | 3 Cardiovascular 心臟血管醫學 | TFDA-00619 | IEC | IEC 60601-2-27:1994 | 1994-03-01 | Medical electrical equipment- Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-27:2011) |
| 173. | 3 Cardiovascular 心臟血管醫學 | TFDA-00620 | IEC | IEC 60601-2-30:1999 | 1999-12-22 | Medical electrical equipment- Part 2-30: Particular requirements for safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment | 本標準已廢除，請參考新標準。(IEC 80601-2-30:2013) |

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| 174. | 3 Cardiovascular 心臟血管醫學 | TFDA-00621 | IEC | IEC 60601-2-34:2000 | 2000-10-01 | Medical electrical equipment –Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-34:2011 ed3.0) |
| 175. | 3 Cardiovascular 心臟血管醫學 | TFDA-00625 | ISO | ISO 5841-1:1989 | 1989-11-15 | Cardiac Pacemakers - Part 1 : Implantable Pacemakers | 本標準已廢除，請參考新標準。(ISO 14708-2:2012) |
| 176. | 3 Cardiovascular 心臟血管醫學 | TFDA-00626 | ISO | ISO 5841-2:2000 | 2000-10-15 | Implants for surgery — Cardiac pacemakers — Part 2:Reporting of clinical performance of populations of pulse generators or leads | 本標準已改版，請參考新版本標準。(ISO 5841-2:2014) |
| 177. | 3 Cardiovascular 心臟血管醫學 | TFDA-00627 | ISO | ISO 5841-3:2000 | 2000-10-15 | Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors [IS-1] for implantable pacemakers | 本標準已改版，請參考新版本標準。(ISO 5841-3:2013) |
| 178. | 3 Cardiovascular 心臟血管醫學 | TFDA-00632 | AAMI | AAMI SP10:2002/A1:2003 | 2002-10-28 | Manual, electronic, or automated sphygmomanometers | 本標準已廢除，請參考新標準。(ISO 81060-1:2007) |
| 179. | 3 Cardiovascular 心臟血管醫學 | TFDA-00704 | AAMI | EC11:1991/(R)2007 | 1991-10-24 | Diagnostic electrocardiographic devices | 本標準已廢除，請參考新標準。(IEC 60601-2-25:2011) |
| 180. | 3 Cardiovascular 心臟血管醫學 | TFDA-00705 | ASTM | F2081-06 | 2009-9 | Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents | 本標準已改版，請參考新版本標準。(ASTM F2081-06/(R)2013) |

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| 181. | 3 Cardiovascular 心臟血管醫學 | TFDA-00706 | IEC | IEC 60601-2-27 Edition 2.0 (2005-08) | 2005-8-29 | Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-27:2011) |
| 182. | 3 Cardiovascular 心臟血管醫學 | TFDA-00707 | IEC | IEC 60601-2-31 Edition 2.0 (2008-03) | 2008-3-26 | Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source | 本標準已改版，請參考新版本標準。(IEC 60601-2-31:2011 ed2.1 Consol. with am1) |
| 183. | 3 Cardiovascular 心臟血管醫學 | TFDA-00779 | ISO | ISO 9919:2005 | 2005-3-15 | Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use | 本標準已廢除，請參考新標準。(ISO 80601-2-61:2011) |
| 184. | 3 Cardiovascular 心臟血管醫學 | TFDA-00904 | ISO | ISO 7199:2009 | 2009-4-15 | Cardiovascular implants and artificial organs -- Blood-gas exchangers (oxygenators) | 本標準已改版，請參考新版本標準。(ISO 7199:2016) |
| 185. | 3 Cardiovascular 心臟血管醫學 | TFDA-00905 | ISO | ISO 15674:2009 | 2009-4-15 | Cardiovascular implants and artificial organs -- Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous | 本標準已改版，請參考新版本標準。(ISO 15674:2016) |

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| 186. | 3 Cardiovascular 心臟血管醫學 | TFDA-00906 | ISO | ISO 15675:2009 | 2009-4-15 | Cardiovascular implants and artificial organs -- Cardiopulmonary bypass systems -- Arterial blood line filters | 本標準已改版，請參考新版本標準。(ISO 15675:2016) |
| 187. | 3 Cardiovascular 心臟血管醫學 | TFDA-00908 | AAMI | EC53:1995/(R)2008 | 2008-12-4 | ECG cables and leadwires | 本標準已改版，請參考新版本標準。(AAMI EC53:2013) |
| 188. | 3 Cardiovascular 心臟血管醫學 | TFDA-00909 | AAMI | EC57:1998/(R)2008 | 2008-12-4 | Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms | 本標準已改版，請參考新版本標準。(AAMI EC57:2012) |
| 189. | 3 Cardiovascular 心臟血管醫學 | TFDA-00910 | ISO | ANSI/AAMI/ISO 81060-2:2009 | 2009-10-30 | Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type | 本標準已改版，請參考新版本標準。(ISO 81060-2:2013) |
| 190. | 3 Cardiovascular 心臟血管醫學 | TFDA-00976 | CEN | EN 1060-1:1995 | 1995-11 | Specification for Non-invasive sphygmomanometers Part 1. General requirements | 本標準已廢除，請參考新標準。(ISO 81060-1:2007) |
| 191. | 3 Cardiovascular 心臟血管醫學 | TFDA-00977 | CEN | EN 1060-3:1997 | 1997-02 | Non-invasive sphygmomanometers Part 3. Supplementary requirements for electro-mechanical blood pressure measuring systems | 本標準已改版，請參考新版本標準。(EN 1060-3:1997+A2:2009) |
| 192. | 3 Cardiovascular 心臟血管醫學 | TFDA-01185 | ASTM | ASTM F138- 00 | 2000-6-10 | Standard Specification for Wrought 18 Chromium 14 Nickel 2.5 | 本標準已改版，請參考新版本標準。(ASTM F138-13) |

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| | | | | | | Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673) | |
| 193. | 3 Cardiovascular 心臟血管醫學 | TFDA-01187 | ASTM | ASTM F2004 - 05(R2010) | 2005 (R2010) | Standard Test Method for Transformation Temperature of Nickel Titanium Alloys by Thermal Analysis | 本標準已改版，請參考新版本標準。(ASTM F2004-16) |
| 194. | 3 Cardiovascular 心臟血管醫學 | TFDA-01190 | ASTM | ASTM F2082 - 06 | 2006-8-15 | Standard Test Method for Determination of Transformation Temperature of Nickel Titanium Shape Memory Alloys by Bend and Free Recovery | 本標準已改版，請參考新版本標準。(ASTM F2082/F2082M-16) |
| 195. | 3 Cardiovascular 心臟血管醫學 | TFDA-01191 | ASTM | ASTM F2129 - 08 | 2008-10-1 | Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices | 本標準已改版，請參考新版本標準。(ASTM F2129-15) |
| 196. | 3 Cardiovascular 心臟血管醫學 | TFDA-01196 | CEN | EN 12006-2:1998+A1:2009 | 2009-11-30 | Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2:Vascular prostheses including cardiac valve conduits | 本標準已被廢除，請參考新標準。(ISO 7198:2017) |

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| 197. | 3 Cardiovascular 心臟血管醫學 | TFDA-01197 | CEN | EN ISO 5840:2009 | 2009-10-31 | Cardiovascular implants - Cardiac valve prostheses | 本標準已改版，請參考新版本標準。(ISO 5840-1, -2, -3) |
| 198. | 3 Cardiovascular 心臟血管醫學 | TFDA-01201 | IEC | IEC 60601-2-27:2011 ed3.0 | 2011-3-30 | Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-27:2011) |
| 199. | 3 Cardiovascular 心臟血管醫學 | TFDA-01212 | ISO | ISO 25539-1:2009 | 2009-7-15 | Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses | 本標準已改版，請參考新版本標準。(ISO 25539-1:2017) |
| 200. | 3 Cardiovascular 心臟血管醫學 | TFDA-01216 | ISO | ISO 7199:2009/Amd 1:2012 | 2012-1-13 | Clarifications for test methodologies, labelling, and sampling schedule | 本標準已改版，請參考新版本標準。(ISO 7199:2016) |
| 201. | 3 Cardiovascular 心臟血管醫學 | TFDA-01221 | OIML | OIML D11:2004 | 2004-1-1 | General requirements for electronic measuring instruments | 本標準已改版，請參考新版本標準。(OIML D11 (2013)) |
| 202. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00057 | ISO | ISO 13294:1997 | 1997-05-01 | Dental Handpieces - Dental Air-Motors | 本標準已廢除，請參考新標準。(ISO 14457:2012) |
| 203. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00058 | ISO | ISO 3336:1993 | 1993-08-15 | Dentistry - Synthetic Polymer Teeth | 本標準已改版，請參考新版本標準。(ISO 22112:2005 ) |
| 204. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00059 | ISO | ISO 4049:2000 | 2000-07-15 | Dentistry - Polymer-Based Filling, Restorative and Luting Materials | 本標準已改版，請參考新版本標準。(ISO 4049:2009 ) |
| 205. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00060 | ISO | ISO 7494:1996 | 1996-03-15 | Dental Units | 本標準已廢除，請參考新標準。(ISO 7494-1:2011) |

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| 206. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00061 | ISO | ISO 7494-2:2003 | 2003/03/01 | Dentistry - Dental units - Part 2: Water and air supply | 本標準已改版，請參考新版本標準。(ISO 7494-2:2015) |
| 207. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00062 | ISO | ISO 7785-1:1997 | 1997-08-01 | Part 1: High-Speed Air Turbine Handpieces | 本標準已廢除，請參考新標準。(ISO 14457:2012) |
| 208. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00063 | ISO | ISO 7785-2:1995 | 1995-08-01 | Part 2: Straight and Geared Angle Handpieces | 本標準已廢除，請參考新標準。(ISO 14457:2012) |
| 209. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00064 | ISO | ISO 9168:1991 | 1991-09-01 | Dental Handpieces - Hose Connectors | 本標準已改版，請參考新版本標準。(ISO 9168:2009 ) |
| 210. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00240 | ISO | ISO 1562:1993 | 1993-12-01 | Dental Casting Gold Alloys | 本標準已廢除，請參考新標準。(ISO 22674:2016) |
| 211. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00241 | ISO | ISO 1563:1990 | 1990-09-01 | Dental Alginate Impression Material | 本標準已廢除，請參考新標準。(ISO 21563:2013) |
| 212. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00242 | ISO | ISO 1564:1995 | 1995-11-01 | Dental Aqueous Impression Materials Based on Agar | 本標準已廢除，請參考新標準。(ISO 21563:2013) |
| 213. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00243 | ISO | ISO 3107:1988 | 1988-11-01 | Dental Zinc Oxide/Eugenol Cements and Zinc Oxide Non-Eugenol Cements | 本標準已改版，請參考新版本標準。(ISO 3107:2011) |
| 214. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00244 | ISO | ISO 6871-1:1994 | 1994-09-15 | Dental base metal casting alloys Part 1: Cobalt-based alloys - TECHNICAL CORRIGENDUM 1:1998 | 本標準已廢除，請參考新標準。(ISO 22674:2016) |

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| 215. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00245 | ISO | ISO 6871-2:1994 | 1994-09-15 | Dental Base Metal Casting Alloys Part 2: Nickel-Based Alloys | 本標準已廢除，請參考新標準。(ISO 22674:2016) |
| 216. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00246 | ISO | ISO 6872:1995+A1:1997 | 1998-06-15 | Dental Ceramic | 本標準已改版，請參考新版本標準。(ISO 6872:2015) |
| 217. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00247 | ISO | ISO 6874:1988 | 1988-11-15 | Dental Resin-Based Pit and Fissue Sealants | 本標準已改版，請參考新版本標準。(ISO 6874:2015) |
| 218. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00248 | ISO | ISO 6876:2001 | 2001-08-15 | Dental Root Canal Sealing Materials | 本標準已改版，請參考新版本標準。(ISO 6876:2012) |
| 219. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00249 | ISO | ISO 6877:1995 | 1995-06-01 | Dental Root-Canal Obturating Points | 本標準已改版，請參考新版本標準。(ISO 6877:2006) |
| 220. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00250 | ISO | ISO 10477:1996 | 2001-03 | Dentistry - Polymer-Based Crown and Bridge Materials | 本標準已改版，請參考新版本標準。(ISO 10477:2004) |
| 221. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00251 | ISO | ISO 11498:1997 | 1997-02-15 | Dental Handpieces: Dental Low Voltage Electrical Motors | 本標準已廢除，請參考新標準。(ISO 14457:2012) |
| 222. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00252 | ISO | ISO 13294:1997 | 1997-05-01 | Dental Handpieces - Dental Air-Motors | 本標準已廢除，請參考新標準。(ISO 14457:2012) |
| 223. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00253 | ISO | ISO 8891:2000 | 1998-12-15 | Dental Casting Alloys with Noble Metal Content of At Least 25% but less than 75% | 本標準已廢除，請參考新標準。(ISO 22674:2016) |
| 224. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00254 | ISO | ISO 9693:1999 | 1999-12-15 | Metal-Ceramic Dental Restorative Systems | 本標準已改版，請參考新版本標準。(ISO 9693-1:2012) |

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| 225. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00255 | ISO | ISO 9917-2:1998 | 1998-07-01 | Dental Water-Based Cements - Part 2: Light-Activated Cements | 本標準已改版，請參考新版本標準。(ISO 9917-2:2010) |
| 226. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00256 | ISO | ISO 13716:1999 | 1999-05-01 | Dentistry - Reversible-Irreversible Hydrocolloid Impression Material Systems | 本標準已廢除，請參考新標準。(ISO 21563:2013) |
| 227. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00257 | ISO | ISO 9917-1:2003 | 2002-05-13 | Dental Water-Based Cements - Part 1: Powder/Liquid Acid-Base Cements - First Edition | 本標準已改版，請參考新版本標準。(ISO 9917-1:2007) |
| 228. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00258 | ISO | ISO 10139-1:1991 | 1991-12-01 | Dentistry - Resilient Lining Materials for Removable Dentures Part 1: Short-Term Materials | 本標準已改版，請參考新版本標準。(ISO 10139-1:2005 & ISO 10139-1:2005/Cor 1:2006) |
| 229. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00259 | ISO | ISO 10139-2:1999 | 1999-10-15 | Dentistry - Resilient lining materials for removable dentures - Part 2: Materials for long-term use | 本標準已改版，請參考新版本標準。(ISO 10139-2:2016) |
| 230. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00260 | ISO | ISO 7494-1:2004 | 2004-11-01 | Dentistry - Dental units - Part 1: General requirements and test methods | 本標準已改版，請參考新版本標準。(ISO 7494-1:2011) |
| 231. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00374 | ANSI | ADA Specification No.96 | 2000 | Dental-Water-Based Cements - Adoption of ISO 9917:1991 | 本標準已改版，請參考新版本標準。(ADA 96-2012 ) |
| 232. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00375 | CEN | EN 1639:1996 | 1996-07-12 | Dentistry - Medical devices for dentistry - Instruments | 本標準已改版，請參考新版本標準。(EN 1639:2009) |

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| 233. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00376 | CEN | EN 1640:1996 | 1996-07-04 | Dentistry - Medical devices for dentistry - Equipment | 本標準已改版，請參考新版本標準。(EN 1640:2009) |
| 234. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00377 | CEN | EN 1641:1996 | 1996-07-04 | Dentistry - Medical devices for dentistry - Materials | 本標準已改版，請參考新版本標準。(EN 1641:2009) |
| 235. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00378 | CEN | EN 1642:1996 | 1996-07-04 | Dentistry - Medical devices for dentistry - Dental implants | 本標準已改版，請參考新版本標準。(EN 1642:2011) |
| 236. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00379 | ISO | ISO 6360-1: 2004 | 2004/04/01 | Dentistry -- Number coding system for rotary instruments -- Part 1: General characteristics | 本標準已改版，請參考新版本標準。(ISO 6360-1 CORR 1:2007) |
| 237. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00380 | ISO | ISO 6360-2: 2004 | 2004-11-01 | Dentistry -- Number coding system for rotary instruments -- Part 2: Shapes | 本標準已改版，請參考新版本標準。(ISO 6360-2:2004/Amd 1:2011) |
| 238. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00386 | ISO | ISO 13397-2: 2005 | 2005-06-15 | Dentistry – Periodontal curettes, dental scalers and excavators – Part 2: Periodontal curettes of Gr-type | 本標準已改版，請參考新版本標準。(ISO 13397-2:2005/Amd1:2012) |
| 239. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00390 | ANSI | ASA S3.6-2004 | 2004-05-13 | Specification for Audiometers | 本標準已改版，請參考新版本標準。(ASA S3.6 (2010) ) |
| 240. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00391 | ANSI | ASA S3.22:2003 | 2003-08-28 | Specification of Hearing Aid Characteristics | 本標準已改版，請參考新版本標準。(ASA S3.22 (2014)) |
| 241. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00392 | ISO | ISO 7405:1997 | 1997- 08-15 | Dentistry -- Preclinical evaluation of biocompatibility of medical devices used in dentistry -- Test methods for dental materials | 本標準已改版，請參考新版本標準。(ISO 7405:2008/Amd 1:2013) |

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| 242. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00393 | ISO | ISO 3107:2004 | 2006-03-01 | Dentistry -- Zinc oxide/eugenol and zinc oxide/non-eugenol cements | 本標準已改版，請參考新版本標準。(ISO 3107:2011) |
| 243. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00680 | CEN | EN 1639:2004 | 2004-6-11 | Dentistry - Medical devices for dentistry - Instruments | 本標準已改版，請參考新版本標準。(EN 1639:2009) |
| 244. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00681 | CEN | EN 1640:2004 | 2004-6-11 | Dentistry - Medical devices for dentistry - Equipment | 本標準已改版，請參考新版本標準。(EN 1640:2009) |
| 245. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00682 | CEN | EN 1641:2004 | 2004-6-14 | Dentistry - Medical devices for dentistry - Materials | 本標準已改版，請參考新版本標準。(EN 1641:2009) |
| 246. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00683 | CEN | EN 1642:2004 | 2004-6-14 | Dentistry - Medical devices for dentistry - Dental implants | 本標準已改版，請參考新版本標準。(EN 1642:2011) |
| 247. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00686 | ISO | ISO 6874:2005 | 2005/8/15 | Dentistry -- Polymer-based pit and fissure sealants | 本標準已改版，請參考新版本標準。(ISO 6874:2015) |
| 248. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00688 | ISO | ISO 22674:2006 | 2006/11/5 | Dentistry -- Metallic materials for fixed and removable restorations and appliances | 本標準已改版，請參考新版本標準。(ISO 22674:2016) |
| 249. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00689 | ISO | ISO 9693:1999/Amd 1:2005 | 2005/10/1 | Metal-ceramic dental restorative systems. | 本標準已被廢除，請參考新標準。(ISO 9693-1:2012) |
| 250. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00874 | ISO | ISO 6872:2008 | 2008-9-1 | Dentistry -- Ceramic materials | 本標準已改版，請參考新版本標準。(ISO 6872:2015) |
| 251. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00876 | ISO | ISO 10139-2:2009 | 2009-8-1 | Dentistry -- Soft lining materials for removable dentures -- Part 2: Materials for long-term use | 本標準已改版，請參考新版本標準。(ISO 10139-2:2016) |

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| 252. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00877 | ISO | ISO 7405:2008 | 2008-12-15 | Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry | 本標準已改版，請參考新版本標準。(ISO 7405:2008/Amd 1:2013) |
| 253. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00879 | ASA | ANSI/ASA S3.22-2009 | 2009-11-10 | Specification of Hearing Aid Characteristics | 本標準已改版，請參考新版本標準。(ASA S3.22 (2014)) |
| 254. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01228 | CNS | CNS 15492 | 2012-7-2 | 牙膏與牙粉 Toothpastes (Dentifrices) | 本標準適用範圍(牙膏與牙粉)不屬於我國醫療器材管理範圍。 |
| 255. | 4 Dental/ENT 牙科學/耳鼻喉科學 | TFDA-01231 | ISO | ISO 14801:2007 | 2007-11-15 | Dentistry — Implants — Dynamic fatigue test for endosseous dental implants - Second Edition | 本標準已改版，請參考新版本標準。(ISO 14801:2016) |
| 256. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00087 | IEC | IEC 60812:1985 | 1985-07 | Analysis technique for system reliability - Procedure for failure modes and effects analysis (FMEA) | 本標準已改版，請參考新版本標準。(IEC 60812: 2006 - Ed. 2.0 ) |
| 257. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00089 | ISO | ISO 14971:2000 | 2000-12-15 | Medical devices - Application of risk management to medical devices | 本標準已改版，請參考新版本標準。(ISO 14971:2007) |
| 258. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00285 | ISO | ISO 14155-1 | 2003-02-15 | Clinical investigation of medical devices for human subjects — Part 1: General requirements | 本標準已廢除，請參考新標準。(ISO 14155:2011/CORR 1:2011) |
| 259. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00286 | ISO | ISO 14155-2 | 2003-05-15 | Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans | 本標準已廢除，請參考新標準。(ISO 14155:2011/CORR 1:2011) |

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| 260. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00432 | ISO | ISO/TR 16142 | 2006/01/15 | Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices | 本標準已被廢除，請參考新標準。(ISO 16142-1:2016) |
| 261. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00437 | ISO | ISO 14971:2000/ Amd 1:2003 | 2003-03-01 | Medical devices -- Application of risk management to medical devices | 本標準已改版，請參考新版本標準。(ISO 14971:2007) |
| 262. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01012 | IEC | IEC 62366:2007 | 2007-10-18 | Medical devices - Application of usability engineering to medical devices | 本標準已被廢除，請參考新標準。(IEC 62366-1:2015) |
| 263. | 5 General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01014 | ISO | ISO 15223-1:2012 | 2012-7-1 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements - Second Edition | 本標準已改版，請參考新版本標準。(ISO 15223-1:2016) |
| 264. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00117 | ISO | ISO 10555-1:1995, A1: 1999 | 1999-07 | Sterile - Single-use Intravascular catheters Part 1: General requirements | 本標準已改版，請參考新版本標準。(ISO 10555-1:2013) |
| 265. | 6 General Plastic Surgery/General Hospital 一般及整形 | TFDA-00118 | ISO | ISO 10555-3:1996, Cor1:2002 | 2002-06-15 | Sterile Single-Use Intravascular Catheters part 3: Central Venous Catheter | 本標準已改版，請參考新版本標準。(ISO 10555-3:2013) |

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| | 外科手術/一般醫院及個人使用裝置 | | | | | | |
| 266. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00119 | ISO | ISO 10555-5:1996, A1:1999 | 2002-06-15 | Sterile, Single-use Intravascular Catheters - Part 5: Over-Needle Peripheral Catheters, Amendment 1 1999-06-15 | 本標準已改版，請參考新版本標準。(ISO 10555-5:2013) |
| 267. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00122 | ISO | ISO 8536-1:2000, A1:2004 | 2000-06-15 | Infusion Equipment for Medical Use - Part 1: Infusion Glass Bottles | 本標準已改版，請參考新版本標準。(ISO 8536-1:2011) |
| 268. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00123 | ISO | ISO 8536-2:2001, Cor 1:2003 | 1992-09-15 | Infusion Equipment for Medical Use - Part 2: Closures for Infusion Bottles | 本標準已改版，請參考新版本標準。(ISO 8536-2:2010 ) |
| 269. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00124 | ISO | ISO 8536-3:1999 | 1992-09-15 | Infusion Equipment for Medical Use - Part 3: Aluminum Caps for Infusion Bottles | 本標準已改版，請參考新版本標準。(ISO 8536-3:2009 ) |
| 270. | 6 General Plastic Surgery/General | TFDA-00125 | ISO | ISO 8536-4:2004 | 1998-02-15 | Infusion Equipment for Medical Use - Part 4: Infusion Sets for Single Use, | 本標準已改版，請參考新版本標準。(ISO |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | Gravity Feed | 8536-4:2010/Amd 1:2013) |
| 271. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00127 | ISO | ISO 8536-6:1995 | 1996-04-01 | Infusion Equipment for Medical Use - Part 6: Freeze Drying Closures for Infusion Bottles | 本標準已改版，請參考新版本標準。(ISO 8536-6:2016) |
| 272. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00128 | ISO | ISO 8536-7:1999 | 1999-09-01 | Infusion Equipment, Caps made of Aluminum-Plastic Combinations for Infusion Bottles | 本標準已改版，請參考新版本標準。(ISO 8536-7:2009 ) |
| 273. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00287 | ISO | ISO 595/1 | 1988-05-15 | Reusable all-glass or metal-and-glass syringes for medical use - Part 1: Dimensions | 本標準已廢除，無取代標準。 |
| 274. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00288 | ISO | ISO 595/2 | 1987-12-15 | Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements and tests | 本標準已廢除，無取代標準。 |

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| 275. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00289 | ISO | ISO 7864:1993 | 1993/05/15 | Sterile hypodermic needles for single use | 本標準已改版，請參考新版本標準。(ISO 7864:2016) |
| 276. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00290 | IEC | IEC 60601-2-19:1996 | 1996-12 | Amendment 1 - Medical electrical equipment Part 2: Particular requirements for safety of baby incubators | 本標準已改版，請參考新版本標準。(IEC 60601-2-19+A11:2011) |
| 277. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00291 | IEC | IEC 60601-2-2:1998 | 2000-11 | Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-2 ed5.0 : 2009) |
| 278. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00292 | ASTM | ASTM D5151-99 | 1999-06 | Standard Test Method for Detection of Holes in Medical Gloves | 本標準已改版，請參考新版本標準。(ASTM D5151-06/(R)2011) |
| 279. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-00293 | ISO | ISO 9626:1991 | 2001-06-01 | Stainless steel needle tubing for the manufacture of medical devices | 本標準已改版，請參考新版本標準。(ISO 9626:2016) |

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| | 個人使用裝置 | | | | | | |
| 280. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00294 | ASTM | ASTM E1112-00 | 2000-08 | Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature | 本標準已改版，請參考新版本標準。(ASTM E1112-00/(R)2011) |
| 281. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00295 | ASTM | ASTM D6124-01 | 2001-09 | Standard Test Method for Residual Powder on Medical Gloves | 本標準已改版，請參考新版本標準。(ASTM D6124-06/(R)2011) |
| 282. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00296 | ASTM | ASTM D3578-01ae2 | 2002-01 | Standard Specification for Rubber Examination Gloves | 本標準已改版，請參考新版本標準。(ASTM D3578-05/(R)2010) |
| 283. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00297 | ASTM | ASTM D3577-01ae2 | 2002-01 | Standard Specification for Rubber Surgical Gloves | 本標準已改版，請參考新版本標準。(ASTM D3577-09/(E)2009) |
| 284. | 6 General Plastic Surgery/General | TFDA-00299 | ASTM | ASTM D3772-01 | 2002-01 | Standard Specification for Natural Rubber Finger Cots | 本標準已改版，請參考新版本標準。(ASTM D3772-15) |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | | |
| 285. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00300 | ASTM | ASTM F882-84(R2002) | 1985-02 | Standard Performance and Safety Specification for Cryosurgical Medical Instruments | 本標準已廢除，無取代標準。 |
| 286. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00301 | ASTM | ASTM F754-00 | 2000-08 | Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube and Rod Shapes | 本標準已改版，請參考新版本標準。(ASTM F754-08) |
| 287. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00302 | ASTM | ASTM F1441-03 | 2003-05 | Standard Specification for Soft-Tissue Expander Devices | 本標準已改版，請參考新版本標準。(ASTM F1441-03/(R)2009) |
| 288. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00303 | ISO | ISO 11608-1:2000 | 2000-12-15 | Pen-injectors for medical use - Part 1: Pen-injectors - Requirements and test methods | 本標準已改版，請參考新版本標準。(ISO 11608-1:2014) |

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| 289. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00304 | ISO | ISO 11608-2:2000 | 2000-12 | Pen-injectors for medical use - Part 2: Needles - Requirements and test methods | 本標準已改版，請參考新版本標準。(ISO 11608-2:2012) |
| 290. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00305 | ISO | ISO 11608-3:2000 | 2000-12-15 | Pen-injectors for medical use - Part 3: Finished cartridges - Requirements and test methods | 本標準已改版，請參考新版本標準。(ISO 11608-3:2012) |
| 291. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00306 | ASTM | ASTM F2172-02 | 2002 | Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers | 本標準已改版，請參考新版本標準。(ASTM F2172-02/(R)2011) |
| 292. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00307 | ASTM | ASTM F2196-02 | 2002 | Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices | 本標準已廢除，請參考新標準。(IEC 80601-2-35:2016) |
| 293. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-00308 | ISO | ISO 1135-4:1998 | 1998-03-15 | Transfusion equipment for medical use - Part 4: Transfusion sets for single use | 本標準已改版，請參考新版本標準。(ISO 1135-4:2015) |

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| | 個人使用裝置 | | | | | | |
| 294. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00457 | ASTM | ASTM D6978-05 | 2005 | Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs | 本標準已改版，請參考新版本標準。(ASTM D6978-05/(R)2013) |
| 295. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00459 | ASTM | ASTM D7160-05 | 2005 | Standard Practice for Determination of Expiration Dating for Medical Gloves | 本標準已改版，請參考新版本標準。(ASTM D7160-16) |
| 296. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00460 | ASTM | ASTM D7161-05 | 2005 | Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions | 本標準已改版，請參考新版本標準。(ASTM D7161-16) |
| 297. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00465 | ISO | ISO 8362-1:2003 | 2003-09-01 | Injection containers and accessories -- Part 1: Injection vials made of glass tubing | 本標準已改版，請參考新版本標準。(ISO 8362-1:2009/Amd1:2015) |
| 298. | 6 General Plastic Surgery/General | TFDA-00466 | ISO | ISO 8362-2:1988 | 1988-12-15 | Injection containers for injectables and accessories -- Part 2: Closures for | 本標準已改版，請參考新版本標準。(ISO 8362-2:2015) |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | injection vials | |
| 299. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00468 | ISO | ISO 8362-4:2003 | 2003-08-01 | Injection containers and accessories -- Part 4: Injection vials made of moulded glass | 本標準已改版，請參考新版本標準。(ISO 8362-4:2011) |
| 300. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00469 | ISO | ISO 8362-5:1995 | 1995-l 2-15 | Injection containers for injectables and accessories -- Part 5: Freeze drying closures for injection vials | 本標準已改版，請參考新版本標準。(ISO 8362-5:2016) |
| 301. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00470 | ISO | ISO 8362-6:1992 | 1992-10-01 | Injection containers for injectables and accessories -- Part 6: Caps made of aluminium-plastics combinations for injection vials | 本標準已改版，請參考新版本標準。(ISO 8362-6:2010 ) |
| 302. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00472 | ISO | ISO 8536-1:2006 | 2006-03-15 | Infusion equipment for medical use -- Part 1: Infusion glass bottles | 本標準已改版，請參考新版本標準。(ISO 8536-1:2011) |

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| 303. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00473 | ISO | ISO 9187-1:2006 | 2006-04-15 | Injection equipment for medical use –Part 1: Ampoules for injectables | 本標準已改版，請參考新版本標準。(ISO 9187-1:2010) |
| 304. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00598 | ISO | ISO 15883-1:2006 | 2006/04/06 | Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests | 本標準已改版，請參考新版本標準。(ISO 15883-1:2006 + A1:2014) |
| 305. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00602 | ASTM | ASTM D6499-03 | 2003-06-01 | Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products | 本標準已改版，請參考新版本標準。(ASTM D6499-16) |
| 306. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00603 | ASTM | ASTM E1104-98(R2003) | 2003-05-10 | Standard Specification for Clinical Thermometer Probe Covers and Sheaths1 | 本標準已改版，請參考新版本標準。(ASTM E1104-98/(R)2009) |
| 307. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-00604 | ASTM | ASTM E1965-98 (R2003) | 2003-05-10 | Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature | 本標準已改版，請參考新版本標準。(ASTM E1965-98/(R)2009) |

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| | 個人使用裝置 | | | | | | |
| 308. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00607 | ASTM | ASTM F881-94 (R2000) | 1994-07-01 | Standard Specification for Silicone Elastomer Facial Implants | 本標準已改版，請參考新版本標準。(ASTM F881-94/(R)2006) |
| 309. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00609 | ASTM | ASTM F1670-03 | 2003-10-01 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood | 本標準已改版，請參考新版本標準。(ASTM F1670-08) |
| 310. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00610 | ASTM | ASTM F1671-03 | 2003-10-01 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System | 本標準已改版，請參考新版本標準。(ASTM F1671/F1671M-13) |
| 311. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00611 | AAMI | AAMI BF7:1989(R2002) | 2002-01-31 | Blood transfusion micro-filters | 本標準已改版，請參考新版本標準。(AAMI BF7:2012) |

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| 312. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00612 | AAMI | AAMI BP22:1994(R2001) | 1994-08-30 | Blood pressure transducers | 本標準已改版，請參考新版本標準。(AAMI BP22:1994(R2011)) |
| 313. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00622 | IEC | IEC 60601-2-38:1996/Amd.1:1999 | 1999-12-17 | Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds | 本標準已廢除，請參考新標準。(IEC 60601-2-52: 2015) |
| 314. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00623 | ISO | ISO 594-1:1986 | 1986/06/15 | Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements | 本標準已被廢除，請參考新標準。(ISO/IEC 80369-7:2016) |
| 315. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00624 | ISO | ISO 594-2:1998 | 1998/09/01 | Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings | 本標準已被廢除，請參考新標準。(ISO/IEC 80369-7:2016) |
| 316. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-00629 | ISO | ISO 8537:1991/Amd.1:2000 | 2000-11-01 | Sterile single-use syringes, with or without needle, for insulin | 本標準已改版，請參考新版本標準。(ISO 8537:2016) |

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| | 個人使用裝置 | | | | | | |
| 317. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00631 | AAMI | AAMI PB70:2003 | 2003-10-23 | Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities | 本標準已改版，請參考新版本標準。(AAMI PB70:2012) |
| 318. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00633 | AAMI | AAMI II:36:1997 | 1997-09-15 | Infant incubators | 本標準已改版，請參考新版本標準。(II36:2004) |
| 319. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00643 | ISO | ISO 10555-5:1996/Amd.1:1999, Cor.1:2002 | 2002-06-15 | Sterile, single-use intravascular catheters - Part 5: Over-needle peripheral catheters | 本標準已改版，請參考新版本標準。(ISO 10555-5:2013) |
| 320. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00710 | AAMI | II36:2004 | 2004-12-9 | Medical electrical equipment - Part 2: Particular requirements for safety of baby incubators | 本標準已廢除，請參考新標準。(IEC 60601-2-19+A11:2011) |
| 321. | 6 General Plastic Surgery/General | TFDA-00711 | AAMI | BF7:1989/(R)2007 | 1989-12-1 | Blood transfusion micro-filters | 本標準已改版，請參考新版本標準。(AAMI BF7:2012) |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | | |
| 322. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00712 | AAMI | BP22:1994/(R)2006 | 1994-11-1 | Blood pressure transducers | 本標準已改版，請參考新版本標準。(AAMI BP22:1994(R2011)) |
| 323. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00713 | ASTM | D3772-01(R2005) | 2005-10 | Standard Specification for Natural Rubber Finger Cots | 本標準已改版，請參考新版本標準。(ASTM D3772-15) |
| 324. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00714 | ASTM | D5151-06 | 2007-1 | ASTM D5151-06 | 本標準已改版，請參考新版本標準。(ASTM D5151-06/(R)2011) |
| 325. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00715 | ASTM | D6499-07 | 2007-12 | Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products | 本標準已改版，請參考新版本標準。(ASTM D6499-16) |

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| 326. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00716 | ASTM | E1112-00(R2006) | 2006-5 | Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature | 本標準已改版，請參考新版本標準。(ASTM E1112-00/(R)2011) |
| 327. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00717 | ASTM | F1671-07 | 2007-2 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System | 本標準已改版，請參考新版本標準。(ASTM F1671/F1671M-13) |
| 328. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00719 | ISO | ISO 10555-1:1995/Amd 2:2004 | 2004-5-15 | Amendment 2-Sterile, single-use intravascular catheters - Part 1: General requirements. | 本標準已改版，請參考新版本標準。(ISO 10555-1:2013) |
| 329. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00720 | ISO | ISO 8537:2007 | 2007-10-1 | Sterile single-use syringes, with or without needle, for insulin | 本標準已改版，請參考新版本標準。(EN/ISO 8537:2016) |
| 330. | 6 General Plastic Surgery/General Hospital 一般及整形 | TFDA-00721 | ISO | ISO 8536-4:2007 | 2007-4-1 | nfusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed | 本標準已改版，請參考新版本標準。(ISO 8536-4:2010/Amd 1:2013) |

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| | 外科手術/一般醫院及個人使用裝置 | | | | | | |
| 331. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00919 | ISO | ISO 8536-6:2009 | 2009-11-15 | Infusion equipment for medical use -- Part 6: Freeze drying closures for infusion bottles | 本標準已改版，請參考新版本標準。(ISO 8536-6:2016) |
| 332. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00921 | IEC | IEC 60601-2-19 ed2.0 : 2009 | 2009-2-20 | Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators | 本標準已改版，請參考新版本標準。(IEC 60601-2-19:2009 + A11:2011) |
| 333. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00922 | IEC | IEC 60601-2-2 ed5.0 : 2009 | 2009-2-23 | Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories | 本標準已改版，請參考新版本標準。(IEC 60601-2-2:2009 + CORR 1:2014) |
| 334. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00924 | ISO | ISO 1135-4:2010 | 2009-4-15 | Transfusion equipment for medical use -- Part 4: Transfusion sets for single use | 本標準已改版，請參考新版本標準。(ISO 1135-4:2015) |

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| 335. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00925 | ISO | ISO 8362-1:2009 | 2009-12-15 | Injection containers and accessories -- Part 1: Injection vials made of glass tubing | 本標準已改版，請參考新版本標準。(ISO 8362-1:2009 + A1:2015) |
| 336. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00926 | ISO | ISO 8362-2:2008 | 2008-10-15 | Injection containers and accessories -- Part 2: Closures for injection vials | 本標準已改版，請參考新版本標準。(ISO 8362-2:2015) |
| 337. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00927 | ISO | ISO 8362-5:2008 | 2008-10-15 | Injection containers and accessories -- Part 5: Freeze drying closures for injection vials | 本標準已改版，請參考新版本標準。(ISO 8362-5:2016) |
| 338. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00932 | AAMI | PB70:2003(R)2009 | 2009-10-21 | Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities | 本標準已改版，請參考新版本標準。(AAMI PB70:2012) |
| 339. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-00979 | CEN | EN 13795-1:2002 | 2002-11 | Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment —Part 1: General | 本標準已改版，請參考新版本標準。(EN 13795:2011+A1:2013) |

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| | 個人使用裝置 | | | | | requirements for manufacturers, processors and products | |
| 340. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00980 | CEN | EN 13795-2:2004 | 2004-11 | Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment —Part 2: Test methods | 本標準已改版，請參考新版本標準。(EN 13795:2011+A1:2013) |
| 341. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00981 | CEN | EN 13795-3:2006 | 2006-06 | Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment —Part 3: Performance requirements and performance levels | 本標準已改版，請參考新版本標準。(EN 13795:2011+A1:2013) |
| 342. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00982 | CEN | EN 12470-5:2003 | 2003-04 | Clinical thermometers —Part 5: Performance of infra-red ear thermometers (with maximum device) | 本標準已廢除，請參考新標準。(ISO 80601-2-56:2017) |
| 343. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00983 | CEN | EN 12470-3:2000 | 2000-01 | Clinical thermometers —Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device | 本標準已廢除，請參考新標準。(ISO 80601-2-56:2017) |
| 344. | 6 General Plastic Surgery/General | TFDA-00985 | CEN | EN 455-2:2000 | 2000-10 | Medical gloves for single use —Part 2: Requirements and testing for | 本標準已改版，請參考新版本標準。(EN 455-2:2015) |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | | | physical properties | |
| 345. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00986 | CEN | EN 455-3:1999 | 1999-12 | Medical gloves for single use —Part 3: Requirements and testing for biological evaluation | 本標準已改版，請參考新版本標準。(EN 455-3:2015) |
| 346. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00987 | ISO | ISO 10282:2002, Cor 1:2005 | 2002-09-15; technical corrigendum 1:2005-06-15 | Single-use sterile rubber surgical gloves -- Specification | 本標準已改版，請參考新版本標準。(ISO 10282:2014) |
| 347. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00989 | ISO | ISO 6009:1992, Cor 1:2008 | 1992/12/01; technical corrigendum 1:2008/03/01 | Hypodermic needles for single use -- Colour coding for identification | 本標準已改版，請參考新版本標準。(ISO 6009:2016) |
| 348. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01262 | ASTM | ASTM D3772-01(R2010) | 2001 (R2010) | Standard Specification for Natural Rubber Finger Cots | 本標準已改版，請參考新版本標準。(ASTM D3772-15) |

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| 349. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01266 | ASTM | ASTM D6499-12 | 2012-7-1 | Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products | 本標準已改版，請參考新版本標準。(ASTM D6499-16) |
| 350. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01268 | ASTM | ASTM D7160-05(R2010) | 2005 (R2010) | Standard Practice for Determination of Expiration Dating for Medical Gloves | 本標準已改版，請參考新版本標準。(ASTM D7160-16) |
| 351. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01269 | ASTM | ASTM D7161-05(R2010) | 2005 (R2010) | Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions | 本標準已改版，請參考新版本標準。(ASTM D7161-16) |
| 352. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01274 | ASTM | ASTM F2052-06e1 | 2006-3-1 | Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment | 本標準已改版，請參考新版本標準。(F2052-14) |
| 353. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及 | TFDA-01285 | CEN | EN 455-2:2009+A2:2013 | 2013-4-30 | Medical gloves for single use. Requirements and testing for physical properties | 本標準已改版，請參考新版本標準。(EN 455-2:2015) |

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| | 個人使用裝置 | | | | | | |
| 354. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01286 | CEN | EN 455-3:2006 | 2006-12-1 | Medical gloves for single use. Requirements and testing for biological evaluation | 本標準已改版，請參考新版本標準。(EN 455-3:2015) |
| 355. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01296 | IEC | IEC 60601-2-46:2010 | 2010-12-16 | Medical electrical equipment – Part 2-46: Particular requirements for the basic safety and essential performance of operating tables | 本標準已改版，請參考新版本標準。(IEC 60601-2-46:2016) |
| 356. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01297 | IEC | IEC 60601-2-50:2009+Corr1:2009 | 2009-3-24 | Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment - Edition 2.0 | 本標準已改版，請參考新版本標準。(IEC 60601-2-50:2016) |
| 357. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01298 | IEC | IEC 60601-2-52:2009+Corr1:2010 | 2010-9-1 | Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds | 本標準已改版，請參考新版本標準。(IEC 60601-2-52: 2015) |
| 358. | 6 General Plastic Surgery/General | TFDA-01299 | IEC | IEC 80601-2-35:2009+Corr2:2 | 2015-2-1 | Medical electrical equipment - Part 2-35: Particular requirements for the | 本標準已改版，請參考新版本標準。(IEC |

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| | Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | | | 015 | | basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use | 80601-2-35:2016) |
| 359. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01303 | ISO | ISO 1135-4:2012 | 2012-3-1 | Transfusion equipment for medical use -- Part 4: Transfusion sets for single use | 本標準已改版，請參考新版本標準。(ISO 1135-4:2015) |
| 360. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01308 | ISO | ISO 80601-2-56:2009 | 2009-10-1 | Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement | 本標準已改版，請參考新版本標準。(ISO 80601-2-56:2017) |
| 361. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01313 | ISO | ISO 9626:1991/Amd 1:2001 | 2001-6-1 | Stainless steel needle tubing for the manufacture of medical devices | 本標準已改版，請參考新版本標準。(ISO 9626:2016) |
| 362. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01318 | IEC | IEC 60601-2-20:2009 ed2.0 | 2009-2-20 | Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators | 本標準已改版，請參考新版本標準。(IEC 60601-2-20:2016) |

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| 363. | 6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-01319 | IEC | IEC 60601-2-21:2009 ed2.0 | 2009-2-23 | Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers | 本標準已改版，請參考新版本標準。(IEC 60601-2-21:2016) |
| 364. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00038 | CEN | EN 13640:2002 | 2002-03 | Stability Testing of In Vitro Diagnostic Reagents | 本標準已廢除，請參考新標準。(ISO 23640:2011) |
| 365. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00039 | CLSI | NCCLS C28-A2:2000 | 2002-06 | How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline - Second Edition | 本標準已改版，請參考新版本標準。(EP28-A3C ) |
| 366. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00040 | CLSI | NCCLS EP10-A2:2002 | 2002-12 | Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline | 本標準已改版，請參考新版本標準。(EP10-A3-AMD) |
| 367. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00041 | CLSI | NCCLS EP12-A:2002 | 2002-08 | User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline | 本標準已改版，請參考新版本標準。(EP12-A2) |
| 368. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00042 | CLSI | NCCLS EP14-A:2001 | 2001-03 | Evaluation of Matrix Effects; Approved Guideline | 本標準已改版，請參考新版本標準。(EP14-A3) |
| 369. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00043 | CLSI | NCCLS EP15-A:2001 | 2001-12 | User Demonstration of Performance for Precision and Accuracy; Approved Guideline | 本標準已改版，請參考新版本標準。(EP15-A3) |

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| 370. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00044 | CLSI | NCCLS EP18-A:2002 | 2002-12 | Quality Management for Unit-Use Testing; Approved Guideline | 本標準已改版，請參考新版本標準。(EP18-A2) |
| 371. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00045 | CLSI | NCCLS EP5-A:1999 | 1999-02 | Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline | 本標準已改版，請參考新版本標準。(EP05-A3) |
| 372. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00046 | CLSI | NCCLS EP7-A:2002 | 2002-12 | Interference Testing in Clinical Chemistry; Approved Guideline | 本標準已改版，請參考新版本標準。(EP7-A2) |
| 373. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00047 | CLSI | NCCLS EP9-A2:2002 | 2002-09 | Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline | 本標準已改版，請參考新版本標準。(EP09-A3 ) |
| 374. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00048 | CLSI | NCCLS GP 10-A:1995 | 1995-12 | Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline | 本標準已廢除，請參考新標準。(EP24-A2) |
| 375. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00050 | CLSI | NCCLS GP16-A2:2001 | 2001-11 | Urinalysis and Collection, Transportation, and Preservation of Urine Specimens - Second Edition; Approved Guideline | 本標準已改版，請參考新版本標準。(GP16-A3) |

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| 376. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00051 | CLSI | NCCLS GP19-A2:2001 | 2003-02 | Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition | 本標準已廢除，請參考新標準。(AUTO13-A2) |
| 377. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00052 | CLSI | NCCLS GP20-A:1996 | 2003-10 | Fine-Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline (1996) | 本標準已改版，請參考新版本標準。(GP20-A2) |
| 378. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00053 | CLSI | NCCLS GP22-A:1999 | 1999-08 | Continuous Quality Improvement: Essential Management Approaches; Approved Guideline | 本標準已改版，請參考新版本標準。(GP22-A3) |
| 379. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00054 | CLSI | NCCLS GP27-A:1999 | 1999-08 | Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline | 本標準已改版，請參考新版本標準。(GP27-A2) |
| 380. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00168 | CLSI | I/LA18-A 1994 | 1994-12 | Specifications for Immunological Testing for Infectious Diseases; Approved Guideline | 本標準已改版，請參考新版本標準。(ILA18-A2 ) |

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| 381. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00169 | CLSI | MM3-A 1995 | 1995-12 | Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline | 本標準已改版，請參考新版本標準。(CLSI MM03 (2015)) |
| 382. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00170 | CLSI | C12-A | 1994-09 | Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard (1994) | 本標準已廢除，請參考新標準。(C46-A2) |
| 383. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00171 | CLSI | C21-A | 1992-03 | Performance Characteristics for Devices Measuring PO2 and PCO2 in Blood Samples; Approved Standard (1992) | 本標準已廢除，請參考新標準。(C46-A2) |
| 384. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00172 | CLSI | C25-A | 1997-01 | Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline (1997) | 本標準已廢除，請參考新標準。(C46-A2) |
| 385. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00173 | CLSI | C27-A | 1993-04 | Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline (1993) | 本標準已廢除，請參考新標準。(C46-A2) |
| 386. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00174 | CLSI | C30-A | 1994-09 | Ancillary (Bedside) Blood Glucose Testing | 本標準已改版，請參考新版本標準。(POCT12-A3) |

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| 387. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00176 | CLSI | H10-A2 | 1995-08 | Solubility Test to Confirm the Presence of Sickling Hemoglobins - Second Edition; Approved Standard (1995) | 本標準已廢除，無取代標準。 |
| 388. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00177 | CLSI | H14-A2 | 1990-12 | Devices for Collection of Skin Puncture Blood Specimens - Second Edition; Approved Guideline (1990) | 本標準已廢除，無取代標準。 |
| 389. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00178 | CLSI | H20-A | 1992-03 | Reference Leucocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard (1992) | 本標準已改版，請參考新版本標準。(H20-A2) |
| 390. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00179 | CLSI | H44-A | 1997-10 | Methods for Reticulocyte Counting (Flow Cytometry and Supravital Dyes); Approved Guideline (1997) | 本標準已改版，請參考新版本標準。(H44-A2) |
| 391. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00180 | CLSI | H47-A | 1996-06 | One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline (1996) | 本標準已改版，請參考新版本標準。(H47-A2) |
| 392. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00181 | CLSI | I/LA2-A | 1996-12 | Quality Assurance for the Indirect Immunoflurescence Test for Autoantibodies to Nuclear Antigen (IF-ANA); Approved Guideline (1996) | 本標準已改版，請參考新版本標準。(ILA2-A2) |

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| 393. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00182 | CLSI | I/LA6-A | 1997-10 | Detection and Quantitation of Rubella IGG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline (1997) | 本標準已廢除，無取代標準。 |
| 394. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00183 | CLSI | I/LA10-A | 1996-12 | Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline (1996) | 本標準已廢除，無取代標準。 |
| 395. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00184 | CLSI | I/LA17-A | 1997-04 | Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Neural Tube Defects; Approved Guideline (1997) | 本標準已廢除，請參考新標準。(I/LA25-A2) |
| 396. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00185 | CLSI | I/LA19-A | 1997-06 | Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (1997) | 本標準已廢除，無取代標準。 |
| 397. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00186 | CLSI | I/LA20-A | 1997-12 | Evaluation Methods and Analytical Performance Characteristics of | 本標準已改版，請參考新版本標準。(CLSI I/LA20-ED3) |

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| | | | | | | Immunological Assays for Human Immunoglobulin E (IgE) Antibodies of Defined Allergen Specificities; Approved Guideline (1997) | |
| 398. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00187 | CLSI | H26-A | 1996-12 | Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard | 本標準已改版，請參考新版本標準。(H26-A2) |
| 399. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00189 | CLSI | H42-A | 1998-12 | Clinical Application of Flow Cytometry: Quality Assurance and Immunophenotyping of Lymphocytes; Approved Guideline | 本標準已改版，請參考新版本標準。(H42-A2) |
| 400. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00190 | CLSI | I/LA21-A | 2002-06 | Clinical Evaluation of Immunoassays; Approved Guideline | 本標準已改版，請參考新版本標準。(ILA21-A2) |
| 401. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00191 | CLSI | M6-A | 1996-12 | Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard | 本標準已改版，請參考新版本標準。(M6-A2) |
| 402. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00193 | CLSI | M22-A2 | 1996-12 | Quality Assurance for Commerically Prepared Microbiological Culture Media - Second Edition; Approved Standard | 本標準已改版，請參考新版本標準。(M22-A3) |
| 403. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00194 | CLSI | M23-A | 1994-06 | Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; | 本標準已改版，請參考新版本標準。(M23-A3) |

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| 404. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00195 | CLSI | M28-A | 1997-12 | Procedures for the Recovery and Identification of Parasites from the Intestinal Tract; Approved Guideline | 本標準已改版，請參考新版本標準。(M28-A2) |
| 405. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00196 | CLSI | MM1-A | 2000-04 | Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline | 本標準已改版，請參考新版本標準。(MM01-A3) |
| 406. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00197 | CLSI | C46-A | 2001-09 | Blood Gas and pH Analysis and Related Measurements; Approved Guideline | 本標準已改版，請參考新版本標準。(C46-A2) |
| 407. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00198 | CLSI | H43-A | 1998-06 | Clinical Applications of Flow Cytometry: Immunophenotyping of Leukemic Cells; Approved Guideline | 本標準已改版，請參考新版本標準。(H43-A2) |
| 408. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00199 | CLSI | MM2-A | 1995-12 | Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline | 本標準已改版，請參考新版本標準。(MM02-A2) |
| 409. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00200 | ISO | ISO 15197 | 2003-05-01 | In vitro diagnostic test systems -Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus | 本標準已改版，請參考新版本標準。(ISO 15197:2013) |
| 410. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00201 | CLSI | DI1-A2 | 1992-07 | Glossary and Guidelines for Immunodiagnostic Procedures, Reagents and Reference | 本標準已廢除，無取代標準。 |

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| | | | | | | Materials-Second Edition | |
| 411. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00202 | CLSI | MM-5A | 2003-04 | Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline | 本標準已改版，請參考新版本標準。(MM05-A2E) |
| 412. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00203 | CLSI | C24-A2 | 1999-02 | Statistical Quality Control for Quantitative Measurements: Principles and Definitions: Approved Guideline - Second Edition (1999) | 本標準已改版，請參考新版本標準。(C24 (2016)) |
| 413. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00206 | CLSI | DI02-A2 | 1993-10 | Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials - Second Edition; Approved Guideline | 本標準已廢除，無取代標準。 |
| 414. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00207 | CLSI | H1-A5 | 2003-12 | Tubes and Additives for Venous Blood Specimen Collection; Approved Standard | 本標準已改版，請參考新版本標準。(H01-A6 ( GP39-A6)) |
| 415. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00208 | CLSI | H4-A4 | 1999-09 | Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard - Fourth Edition | 本標準已改版，請參考新版本標準。(H04-A6) |
| 416. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00212 | CLSI | LA01-A2 | 1994-12 | Assessing the Quality of Radioimmunoassay Systems - Second Edition; Approved Guideline | 本標準已廢除，無取代標準。 |

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| 417. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00213 | CLSI | M2-A8 | 2003-01 | Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard - 8th Edition | 本標準已改版，請參考新版本標準。(M02-A12) |
| 418. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00214 | CLSI | M7-A6 | 2003-01 | Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically`; Approved Standard - Sixth Edition | 本標準已改版，請參考新版本標準。(M07-A10) |
| 419. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00215 | CLSI | M11-A6 | 2004-01 | Methods for Antimicrobial Susceptibility Tests of Anaerobic Bacteria; Approved Standard -- Sixth Edition | 本標準已改版，請參考新版本標準。(M11-A8) |
| 420. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00216 | CLSI | M24-A | 2003-04 | Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard | 本標準已改版，請參考新版本標準。(M24-A2) |
| 421. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00218 | CLSI | M27-A | 1999-06 | Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard (1997). | 本標準已改版，請參考新版本標準。(M27-S4 ) |
| 422. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00220 | CLSI | RS2-A | 1998-10 | The National Reference System for the Clinical Laboratory (NRSCL) Aspartate Aminotransferase (AST) | 本標準已廢除，無取代標準。 |
| 423. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00221 | CLSI | RS3-A | 1987-09 | The National Reference System for the Clinical Laboratory (NRSCL) | 本標準已廢除，無取代標準。 |

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| 424. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00222 | CLSI | RS5-A2 | 1993-12 | The National Reference System for the Clinical Laboratory (NRSCL) Total Protein | 本標準已廢除，無取代標準。 |
| 425. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00223 | CLSI | RS6-A | 1989-07 | The National Reference System for the Clinical Laboratory (NRSCL) Total Bilirubin | 本標準已廢除，無取代標準。 |
| 426. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00318 | CEN | EN 375:2001 | 2000-12-06 | Information supplied by the manufacturer with in vitro diagnostic reagents for professional use | 本標準已廢除，請參考新標準。(ISO 18113-2:2011) |
| 427. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00322 | CLSI | MM9-A | 2004-12-20 | Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine | 本標準已改版，請參考新版本標準。(MM09-A2) |
| 428. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00323 | CLSI | H21-A4 | 2003-12-01 | Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline - Fourth Edition | 本標準已改版，請參考新版本標準。(H21-A5 ) |
| 429. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00326 | CLSI | C3-A4 | 2006-06-16 | Preparation and Testing of Reagent Water in the Clinical Laboratory | 本標準已廢除，請參考新標準。(GP40-A4-AMD) |
| 430. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00327 | CLSI | C49-P | 2006-06-20 | Analysis of body fluids in clinical laboratory | 本標準已改版，請參考新版本標準。(C49-A) |
| 431. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00330 | CLSI | MM10-P | 2005-06-08 | Genotyping for infectious diseases: Identification and characterization | 本標準已改版，請參考新版本標準。(MM10-A) |

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| 432. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00331 | CLSI | MM11-P | 2006-05-31 | Molecular methods for bacterial strain typing | 本標準已改版，請參考新版本標準。(MM11-A) |
| 433. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00335 | CLSI | C43-A | 2002-11-01 | Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs; Approved Guideline | 本標準已改版，請參考新版本標準。(C43-A2) |
| 434. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00338 | CLSI | H17-A | 1998-12-01 | Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard | 本標準已廢除，請參考新標準。(C61-A) |
| 435. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00340 | CLSI | MM4-A | 1999-12-01 | Quality Assurance for Immunocytochemistry; Approved Guideline | 本標準已廢除，無取代標準。 |
| 436. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00341 | CLSI | MM6-A | 2003-10-20 | Quantitative Molecular Methods for Infectious Diseases; Proposed Guideline | 本標準已改版，請參考新版本標準。(MM06-A2) |
| 437. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00342 | CLSI | MM14-A | 2001-12 | Proficiency Testing (External Quality Assessment) for Molecular Methods; Approved Guideline | 本標準已改版，請參考新版本標準。(MM14-A2 ) |
| 438. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00343 | CLSI | POCT1-A | 2005-08-19 | Point-of-Care Connectivity; Approved Standard | 本標準已改版，請參考新版本標準。(POCT1-A2 ) |
| 439. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00480 | ISO | ISO 22870:2006 | 2006/02/03 | Point-of-care testing (POCT) -- Requirements for quality and competence | 本標準已改版，請參考新版本標準。(ISO 22870:2016 - Point-of-care testing (POCT) - Requirements for q |

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| 440. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00482 | CLSI | POCT2-P | 2007-03-08 | Implementation Guide of POCT1 for Healthcare Providers; Proposed Guideline | 本標準已改版，請參考新版本標準。(POCT02-A) |
| 441. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00483 | CLSI | POCT4-A2 | 2006/08/29 | Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline - Second Edition | 本標準已改版，請參考新版本標準。(CLSI POCT4-A3) |
| 442. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00486 | ANSI | AST3-A | 1999-02-01 | Wellness Testing Using IVD Devices; Approved Guideline | 本標準已廢除，無取代標準。 |
| 443. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00487 | ANSI | AST4-A2 | 2005-05-01 | Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition | 本標準已廢除，請參考新標準。(CLSI POCT13 (2015)) |
| 444. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00495 | CLSI | C40-A | 2001-06-01 | Analytical Procedures for the Determination of Lead in Blood and Urine; Approved Guideline | 本標準已改版，請參考新版本標準。(C40-A2) |
| 445. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00497 | CLSI | EP17-A | 2004-10-20 | Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline | 本標準已改版，請參考新版本標準。(EP17-A2) |
| 446. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00498 | CLSI | EP21-A | 2003/04/20 | Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline | 本標準已改版，請參考新版本標準。(CLSI EP21 2016.07.01) |
| 447. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00499 | CLSI | GP10-A | 1995-12-01 | Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) | 本標準已廢除，請參考新標準。(EP24-A2 ) |

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| 448. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00500 | CLSI | M6-A | 2003-10-20 | Protocols for Evaluating Dehydrated Mueller–Hinton Agar; Approved Standard | 本標準已改版，請參考新版本標準。(M6-A2) |
| 449. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00501 | CLSI | M7-A7 | 2006-01-03 | Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Seventh Edition | 本標準已改版，請參考新版本標準。(M07-A10) |
| 450. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00504 | CLSI | M23-A2 | 2001-05-01 | Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline—Second Edition | 本標準已改版，請參考新版本標準。(M23-A3) |
| 451. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00505 | CLSI | M24-A | 2003-04-01 | Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard | 本標準已改版，請參考新版本標準。(M24-A2) |
| 452. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00507 | CLSI | M31-S1 | 2004-05-01 | Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Informational Supplement | 本標準已廢除，請參考新標準。(VET01-A4) |

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| 453. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00508 | CLSI | M31-A2 | 2002-05-01 | Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard—Second Edition | 本標準已廢除，請參考新標準。(VET01-A4) |
| 454. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00510 | CLSI | M39-A | 2002-05-01 | Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline | 本標準已改版，請參考新版本標準。(M39-A4) |
| 455. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00511 | CLSI | M45-P | 2005-10-01 | Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Proposed Guideline | 本標準已改版，請參考新版本標準。(CLSI M45-A3:2015) |
| 456. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00649 | CLSI | C24-A3 | 2006/6/23 | Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline-Third Edition | 本標準已改版，請參考新版本標準。(CLSI C24 2016.09.01) |
| 457. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00657 | CLSI | M11-A7 | 2007-1-3 | Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard - Seventh Edition | 本標準已改版，請參考新版本標準。(M11-A8) |

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| 458. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00659 | CLSI | MM3-A2 | 2006/2/17 | Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline - Second Edition | 本標準已改版，請參考新版本標準。(MM03-Ed3:2015) |
| 459. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00662 | CLSI | EP14-A2 | 2005/1/20 | Evaluation of Matrix Effects; Approved Guideline-Second Edition | 本標準已改版，請參考新版本標準。(EP14-A3) |
| 460. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00663 | CLSI | EP15-A2 | 2006/4/5 | User Verification of Performance for Precision and Trueness; Approved Guideline - Second Edition | 本標準已改版，請參考新版本標準。(EP15-A3 ) |
| 461. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00664 | CLSI | EP5-A2 | 2004/8/20 | Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition | 本標準已改版，請參考新版本標準。(EP05-A3) |
| 462. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00665 | CLSI | GP22-A2 | 2004-11-20 | Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition | 本標準已改版，請參考新版本標準。(GP22-A3) |
| 463. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00733 | CLSI | H49-A | 2004-7-1 | Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline | 本標準已廢除，請參考新標準。(POCT14-A) |
| 464. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00734 | CLSI | C30-A2 | 2002-8-1 | Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities | 本標準已廢除，請參考新標準。(POCT12-A3) |
| 465. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00830 | CLSI | C28-A3 | 2008-11-24 | How to Define and Determine Reference Intervals in the Clinical | 本標準已廢除，請參考新標準。(EP28-A3C ) |

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| 466. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00831 | CLSI | EP10-A3 | 2006-11-28 | Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline - Third Edition | 本標準已改版，請參考新版本標準。(EP10-A3-AMD) |
| 467. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00833 | CLSI | EP09-A2-IR | 2010-7-30 | Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition (Interim Revision) | 本標準已廢除，請參考新標準。(EP09-A3 ) |
| 468. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00836 | CLSI | H47-A2 | 2005/5/30 | One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline - Second Edition | 本標準已改版，請參考新版本標準。(H47 2008.05.01) |
| 469. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00837 | CLSI | I/LA25-A | 2004-12-20 | Maternal Serum Screening; Approved Standard | 本標準已改版，請參考新版本標準。(I/LA25-A2) |
| 470. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00838 | CLSI | I/LA20-A2 | 2009/3/4 | Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities; Approved Guideline-Second Edition | 本標準已改版，請參考新版本標準。(CLSI I/LA20-ED3 2016.10.01) |

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| 471. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00842 | CLSI | MM01-A2 | 2006-6-23 | Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline-Second Edition | 本標準已改版，請參考新版本標準。(MM01-A3) |
| 472. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00843 | CLSI | MM02-A2 | 2002-8-1 | Immunoglobin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline - Second Edition | 本標準已廢除，無取代標準。 |
| 473. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00844 | CLSI | H04-A6 | 2008-9-23 | Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Sixth Edition | 本標準已廢除，請參考新標準。(GP42-A6) |
| 474. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00845 | CLSI | M02-A10 | 2009-1 | Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard - Tenth Edition | 本標準已改版，請參考新版本標準。(M02-A12) |
| 475. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00846 | CLSI | M07-A8 | 2009-1 | Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard- Eighth Edition | 本標準已改版，請參考新版本標準。(M07-A10) |
| 476. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00847 | CLSI | M27-A3 | 2008-4-28 | Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard - Third Edition | 本標準已改版，請參考新版本標準。(M27-S4 ) |

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| 477. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00854 | CLSI | M31-A3 | 2008-2-29 | Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard - Third Edition | 本標準已廢除，請參考新標準。(VET01-A4) |
| 478. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00855 | CLSI | M39-A3 | 2009-2-5 | Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Third Edition | 本標準已改版，請參考新版本標準。(M39-A4) |
| 479. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-00856 | CLSI | M45-A | 2006-5-30 | Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline | 本標準已改版，請參考新版本標準。(CLSI M45-A3:2015) |
| 480. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01126 | CLSI | M45-A2 | 2010-8-1 | Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline | 本標準已改版，請參考新版本標準。(CLSI M45-A3) |
| 481. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01132 | CLSI | POCT13-A2 | 2005-5-1 | Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline - Second Edition | 本標準已改版，請參考新版本標準。(CLSI POCT13-A3) |

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| 482. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01136 | CLSI | VET01-S2 | 2013-7-1 | English -- Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard, Second Informational Supplement - Vol 33; No 7 | 本標準已改版，請參考新版本標準。(CLSI VET01-S3) |
| 483. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01141 | IEC | IEC 61010-1:2010+Corr1:2010 | 2010-6-10 | Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements | 本標準已改版，請參考新版本標準。(IEC 61010-1:2017) |
| 484. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01142 | IEC | IEC 61010-2-101:2002 | 2002-1-9 | Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101: Particular Requirements for in Vitro Diagnostic (IVD) Medical Equipment - First Edition | 本標準已改版，請參考新版本標準。(IEC 61010-2-101:2015) |
| 485. | 7 In Vitro Diagnostics 體外診斷醫療器材 | TFDA-01153 | ISO | ISO 23640:2011 | 2011 | In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents | 本標準已改版，請參考新版本標準。(ISO 23640:2011) |
| 486. | 8 Materials 材料 | TFDA-00066 | ISO | ISO 5832-1:1997 | 1997-07-15 | Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel | 本標準已改版，請參考新版本標準。(ISO 5832-1:2016) |

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| 487. | 8 Materials 材料 | TFDA-00068 | ISO | ISO 5832-3:1996 | 1996/07/01 | Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy | 本標準已改版，請參考新版本標準。(ISO 5832-3:2016) |
| 488. | 8 Materials 材料 | TFDA-00069 | ISO | ISO 5832-4:1996 | 1996/07/01 | Implants for surgery -- Metallic materials -- Part 4: Cobalt-chromium-molybdenum casting alloy | 本標準已改版，請參考新版本標準。(ISO 5832-4:2014) |
| 489. | 8 Materials 材料 | TFDA-00070 | ISO | ISO 5832-5:1993 | 1993-09-15 | Implants for surgery -- Metallic materials -- Part 5: Wrought cobalt-chromium-tungsten-nickel alloy | 本標準已改版，請參考新版本標準。(ISO 5832-5:2005) |
| 490. | 8 Materials 材料 | TFDA-00072 | ISO | ISO 5832-7:1994 | 1994/02/01 | Implants for surgery -- Metallic materials -- Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy | 本標準已改版，請參考新版本標準。(ISO 5832-7:2016) |
| 491. | 8 Materials 材料 | TFDA-00074 | ISO | ISO 5832-9:1992 | 1992-10-15 | Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel | 本標準已改版，請參考新版本標準。(ISO 5832-9:2007 ) |
| 492. | 8 Materials 材料 | TFDA-00075 | ISO | ISO 5832-11:1994 | 1994/09/01 | Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium | 本標準已改版，請參考新版本標準。(ISO 5832-11:2014) |

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| 493. | 8 Materials 材料 | TFDA-00076 | ISO | ISO 5832-12:1996 | 1996-07-01 | Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy | 本標準已改版，請參考新版本標準。(ISO 5832-12:2007, Cor 1:2008 ) |
| 494. | 8 Materials 材料 | TFDA-00077 | ISO | ISO 5834-1:1998 | 1998-08-01 | Implants for surgery -- Ultra-high molecular weight polyethylene -- Part 1: Powder form | 本標準已改版，請參考新版本標準。(ISO 5834-1:2005, Cor 1:2007 ) |
| 495. | 8 Materials 材料 | TFDA-00078 | ISO | ISO 5834-2:1998 | 1998-08-01 | Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 2: Moulded Forms | 本標準已改版，請參考新版本標準。(ISO 5834-2:2011) |
| 496. | 8 Materials 材料 | TFDA-00079 | ISO | ISO 6474-1994 | 1994-02-01 | Implants for surgery -- Ceramic materials based on high purity alumina | 本標準已改版，請參考新版本標準。(ISO 6474-1:2010 ) |
| 497. | 8 Materials 材料 | TFDA-00261 | ISO | ISO 14708-1: 2000 | 2000/11/15 | Implants for surgery — Active implantable medical devices —Part 1: General requirements for safety, marking and for information to be provided by the manufacturer | 本標準已改版，請參考新版本標準。(ISO 14708-1:2014) |

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| 498. | 8 Materials 材料 | TFDA-00395 | ISO | ISO 5834-2: 2006 | 2006-04-01 | Implants for surgery – Ultra-high molecular-weight polyethylene – Part 2: Moulded forms | 本標準已改版，請參考新版本標準。(ISO 5834-2:2011) |
| 499. | 8 Materials 材料 | TFDA-00880 | ISO | ISO 5832-1:2007/Cor 1:2008 | 2007/06/15, Technical Corrigendum 1:2008/04/15 | Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel | 本標準已改版，請參考新版本標準。(ISO 5832-1:2016) |
| 500. | 8 Materials 材料 | TFDA-00949 | AATCC | AATCC 42:2000 | 2000 | Water Resistance: Impact Penetration Test | 本標準已改版，請參考新版本標準。(AATCC 42-2013) |
| 501. | 8 Materials 材料 | TFDA-00950 | AATCC | AATCC 127:1998 | 1998 | Water Resistance: Hydrostatic Pressure Test | 本標準已改版，請參考新版本標準。(AATCC 127-2008) |
| 502. | 8 Materials 材料 | TFDA-00951 | AAMI | ST65:2000 | 2000-1-20 | Processing of reusable surgical textiles for use in health care facilities | 本標準已改版，請參考新版本標準。(ST65:2008) |
| 503. | 8 Materials 材料 | TFDA-00953 | ISO | ISO 139:2005 | 2005-1-15 | Textiles -- Standard atmospheres for conditioning and testing | 本標準已改版，請參考新版本標準。(ISO 139:2005/Amd 1:2011) |
| 504. | 8 Materials 材料 | TFDA-01088 | ASTM | ASTM F136-12a | 2012-12-1 | Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) | 本標準已改版，請參考新版本標準。(ASTM F136-13) |

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| 505. | 8 Materials 材料 | TFDA-01092 | ASTM | ASTM F2026-12 | 2012-10-1 | Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications | 本標準已改版，請參考新版本標準。(ASTM F2026-16) |
| 506. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00056 | IEC | IEC 60601-2-18:1996 | 2000-07 | Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-18 ed3.0 : 2009) |
| 507. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00129 | ISO | ISO 4074:2002 | 2002/02/15 | Natural latex rubber condoms - Requirements and test methods | 本標準已改版，請參考新版本標準。(ISO 4074:2014) |
| 508. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00452 | ISO | ISO 8637:2004 | 2004-10-01 | Cardiovascular implants and artificial organs-Haemodialysers, haemofilters and haemoconcentrators | 本標準已改版，請參考新版本標準。(ISO 8637-1:2017) |
| 509. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00453 | ISO | ISO 8638:2004 | 2004-10-01 | Extracorporeal blood circuit for haemodialysers, haemofilters and haemoconcentrators | 本標準已改版，請參考新版本標準。(ISO 8638:2010 ) |
| 510. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00634 | AAMI | AAMI RD5:2003 | 2007-11-08 | Hemodialysis systems | 本標準已廢除，請參考新標準。(IEC 60601-2-16:2012 ) |

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| 511. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00635 | AAMI | AAMI RD16:2007 | 2007-07-18 | Cardiovascular implants and artificial organs - Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators | 本標準已廢除，請參考新標準。(ISO 8637-1:2017) |
| 512. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00636 | AAMI | AAMI RD17:2007 | 2007-07-19 | Cardiovascular implants and artificial organs - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters | 本標準已廢除，請參考新標準。(ISO 8638:2010 ) |
| 513. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00637 | AAMI | AAMI RD47:2002 & RD47:2002/A1:2003 | 2003-04-25 | Reuse of hemodialyzers | 本標準已改版，請參考新版本標準。(AAMI RD47:2008/(R)2013) |
| 514. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00638 | AAMI | AAMI RD52:2004 | 2004-09-16 | Dialysate for hemodialysis | 本標準已廢除，請參考新標準。(AAMI 23500:2014) |
| 515. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00639 | AAMI | AAMI RD61:2006 | 2007-05-04 | Concentrates for hemodialysis | 本標準已廢除，請參考新標準。(ISO 13958:2014) |
| 516. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00640 | AAMI | AAMI RD62:2006 | 2007-01-06 | Water treatment equipment for hemodialysis applications | 本標準已廢除，請參考新標準。(ISO 26722:2014) |

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| 517. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00732 | ISO | ISO 4074:2002/Cor 2:2008 | 2008/4/15 | Natural latex rubber condoms - Requirements and test methods, Technical Corrigendum 2. | 本標準已改版，請參考新版本標準。(ISO 4074:2014) |
| 518. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00911 | ISO | ISO 8637:2010 | 2010-7-1 | Cardiovascular implants and extracorporeal systems -- Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators | 本標準已改版，請參考新版本標準。(ISO 8637-1:2017) |
| 519. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00913 | AAMI | RD5:2003/(R)2008 | 2008-5-1 | Hemodialysis systems | 本標準已廢除，請參考新標準。(IEC 60601-2-16:2012 ) |
| 520. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00915 | AAMI | RD52:2004/(R)2010 (incl A1 through A4) | 2010-4-22 | Dialysate for hemodialysis (consolidated text with Amendments 1 through 4 included) | 本標準已廢除，請參考新標準。(AAMI 23500:2014) |
| 521. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-00999 | ISO | ISO 11663:2009 | 2009-04-15 | Quality of dialysis fluid for haemodialysis and related therapies | 本標準已改版，請參考新版本標準。(ISO 11663:2014) |
| 522. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01000 | ISO | ISO 13958:2009 | 2009-04-15 | Concentrates for haemodialysis and related therapies | 本標準已改版，請參考新版本標準。(ISO 13958:2014) |

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| 523. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01001 | ISO | ISO 13959:2009 | 2009-04-15 | Water for haemodialysis and related therapies | 本標準已改版，請參考新版本標準。(ISO 13959:2014) |
| 524. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01002 | ISO | ISO 26722:1999 | 2009-04-15 | Water treatment equipment for haemodialysis applications and related therapies | 本標準已改版，請參考新版本標準。(ISO 26722:2014) |
| 525. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01248 | ASTM | ASTM D1894-11 | 2011-9-1 | Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting | 本標準已改版，請參考新版本標準。(ASTM D1894-14) |
| 526. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01249 | ASTM | ASTM D412-06a(R2013) | 2006 (R2013) | Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension | 本標準已改版，請參考新版本標準。(ASTM D412-15) |
| 527. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01250 | ASTM | ASTM F1828-97/(R)2013 | 1905-7-5 | Standard Specification for Ureteral Stents | 本標準已改版，請參考新版本標準。(ASTM F1828-17) |
| 528. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01251 | CEN | EN 1283:1996 | 1996-10-31 | Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits | 本標準已被廢除，請參考新版本標準。(ISO 8637-1:2017)。 |

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| 529. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01255 | ISO | ISO 8009:2004/Amd 1:2012 | 2012-2-15 | Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests AMENDMENT 1 - First Edition | 本標準已改版，請參考新版本標準。(ISO 8009:2014) |
| 530. | 9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學 | TFDA-01256 | ISO | ISO 8637:2010/Amd 1:2013 | 2013-4-1 | Revision to Figure 2 -- Main fitting dimensions of dialysis fluid inlet and outlet ports | 本標準已被廢除，請參考新標準。(ISO 8637-1:2017) |
| 531. | 10 Ophthalmic 眼科學 | TFDA-00130 | ISO | ISO 10338:1996 | 1996-07-15 | Optics and optical instruments -- Contact lenses -- Determination of curvature | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |
| 532. | 10 Ophthalmic 眼科學 | TFDA-00131 | ISO | ISO 10339:1997 | 1997-09-15 | Ophthalmic optics -- Contact lenses -- Determination of water content of hydrogel lenses | 本標準已廢除，請參考新標準。(ISO 18369-4:2006 ) |
| 533. | 10 Ophthalmic 眼科學 | TFDA-00132 | ISO | ISO 10340:1995 | 1995-08-01 | Optics and optical instruments -- Contact lenses -- Method for determining the extractable substances | 本標準已廢除，請參考新標準。(ISO 18369-4:2006 ) |
| 534. | 10 Ophthalmic 眼科學 | TFDA-00133 | ISO | ISO 10344:1996 | 1996-09-01 | Optics and optical instruments -- Contact lenses -- Saline solution for contact lens testing | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |
| 535. | 10 Ophthalmic 眼科學 | TFDA-00134 | ISO | ISO 11981:1999 | 2002-02-15 | Ophthalmic optics -- Contact lenses and contact lens care products -- | 本標準已改版，請參考新版本標準。(ISO 11981:2009) |

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| | | | | | | Determination of physical compatibility of contact lens care products with contact lenses | |
| 536. | 10 Ophthalmic 眼科學 | TFDA-00135 | ISO | ISO 9913-1:1996 | 1996-1l-01 | Optics and optical instruments -- Contact lenses -- Part 1: Determination of oxygen permeability and transmissibility with the FATT method | 本標準已廢除，請參考新標準。(ISO 18369-4:2006 ) |
| 537. | 10 Ophthalmic 眼科學 | TFDA-00136 | ISO | ISO 9913-2:2000 | 2000-02-15 | Optics and optical instruments -- Contact lenses -- Part 2: Determination of oxygen permeability and transmissibility by the coulometric method | 本標準已廢除，請參考新標準。(ISO 18369-4:2006 ) |
| 538. | 10 Ophthalmic 眼科學 | TFDA-00137 | ISO | ISO 8321-1:2002 | 2002-09-15 | Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 1: Rigid corneal and scleral contact lenses | 本標準已廢除，請參考新標準。(ISO 18369-1:2006/amd 1:2009) |
| 539. | 10 Ophthalmic 眼科學 | TFDA-00138 | ISO | ISO 8321-2:2000 | 2000-03-01 | Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 2: Single-vision hydrogel contact lenses | 本標準已廢除，請參考新標準。(ISO 18369-2:2012) |
| 540. | 10 Ophthalmic 眼科學 | TFDA-00139 | ISO | ISO 8599:1994 | 19944 2-01 | Optics and optical instruments -- Contact lenses -- Determination of | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |

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| 541. | 10 Ophthalmic 眼科學 | TFDA-00140 | ISO | ISO 9337-1:1999 | 1999-05-01 | Contact lenses -- Determination of back vertex power -- Part 1: Method using focimeter with manual focusing | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |
| 542. | 10 Ophthalmic 眼科學 | TFDA-00141 | ISO | ISO 9338:1996 | 1996-10-15 | Optics and optical instruments -- Contact lenses -- Determination of the diameters | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |
| 543. | 10 Ophthalmic 眼科學 | TFDA-00142 | ISO | ISO 9339-1:1996 | 1996-08-15 | Optics and optical instruments -- Contact lenses -- Determination of the thickness -- Part 1: Rigid contact lenses | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |
| 544. | 10 Ophthalmic 眼科學 | TFDA-00143 | ISO | ISO 9339-2:1998 | 2000-04-15 | Optics and optical instruments -- Contact lenses -- Determination of thickness -- Part 2: Hydrogel contact lenses | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |
| 545. | 10 Ophthalmic 眼科學 | TFDA-00144 | ISO | ISO 9340:1996 | 1996-08-15 | Optics and optical instruments -- Contact lenses -- Determination of strains for rigid contact lenses | 本標準已廢除，無取代標準。 |
| 546. | 10 Ophthalmic 眼科學 | TFDA-00145 | ISO | ISO 9341:1996 | 1996-08-15 | Optics and optical instruments -- Contact lenses -- Determination of inclusions and surface imperfections for rigid contact lenses | 本標準已廢除，請參考新標準。(ISO 18369-3:2006 ) |

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| 547. | 10 Ophthalmic 眼科學 | TFDA-00146 | ISO | ISO 9394:1998 | 1998-08-15 | Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of biocompatibility by ocular study using rabbit eyes | 本標準已改版，請參考新版本標準。(ISO 9394:2012) |
| 548. | 10 Ophthalmic 眼科學 | TFDA-00147 | ISO | ISO 9914:1995 | 1995-l 2-01 | Optics and optical instruments -- Contact lenses -- Determination of refractive index of contact lens materials | 本標準已廢除，請參考新標準。(ISO 18369-4:2006 ) |
| 549. | 10 Ophthalmic 眼科學 | TFDA-00148 | ISO | ISO 11987:1997 | 1997-12-01 | Ophtalmic optics -- Contact lenses -- Determination of shelf-life | 本標準已改版，請參考新版本標準。(ISO 11987:2012) |
| 550. | 10 Ophthalmic 眼科學 | TFDA-00149 | ISO | ISO 14534:2002 | 2002-06-15 | Ophthalmic optics -- Contact lenses and contact lens care products -- Fundamental requirements | 本標準已改版，請參考新版本標準。(ISO 14534:2011) |
| 551. | 10 Ophthalmic 眼科學 | TFDA-00150 | ISO | ISO 14730:2000 | 2000/09/15 | Ophthalmic optics -- Contact lens care products -- Antimicrobial preservative efficacy testing and guidance on determining discard date | 本標準已改版，請參考新版本標準。(ISO 14730:2014) |
| 552. | 10 Ophthalmic 眼科學 | TFDA-00461 | ANSI | ANSI Z80.7-2002: | 2002 | Ophthalmics - Intraocular Lenses | 本標準已改版，請參考新版本標準。(ANSI Z80.7, 2013) |
| 553. | 10 Ophthalmic 眼科學 | TFDA-00462 | ANSI | ANSI Z80.20-2004: | 2004 | Ophthalmics -- Contact lenses -- Standard Terminology, Tolerances, Measurements and Physicochemical Properties | 本標準已改版，請參考新版本標準。(ANSI Z80.20-2010) |

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| 554. | 10 Ophthalmic 眼科學 | TFDA-00725 | ISO | ISO 18369-2:2006 | 2006-8-15 | Ophthalmic optics -- Contact lenses -- Part 2: Tolerances | 本標準已改版，請參考新版本標準。(ISO 18369-2:2012) |
| 555. | 10 Ophthalmic 眼科學 | TFDA-00991 | ISO | ISO 11986:1999 | 1999-05-01 | Ophthalmic optics -- Contact lenses and contact lens care products -- Guidelines for determination of preservative uptake and release | 本標準已改版，請參考新版本標準。(ISO 11986:2010) |
| 556. | 10 Ophthalmic 眼科學 | TFDA-00994 | ISO | ISO 8980-3:2003 | 2003-10-01 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 3: Transmittance specifications and test methods | 本標準已改版，請參考新版本標準。(ISO 8980-3:2013) |
| 557. | 10 Ophthalmic 眼科學 | TFDA-01326 | ANSI | ANSI Z80.20-2010 | 2010-12-6 | Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemcial Properties | 本標準已被廢除，請參考新標準。(ANSI Z80.36 :2016) |
| 558. | 10 Ophthalmic 眼科學 | TFDA-01329 | IEC | IEC 80601-2-58:2008 | 2008-10-21 | Medical electrical equipment -- Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery | 本標準已改版，請參考新版本標準。(IEC 80601-2-58:2014) |

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| 559. | 10 Ophthalmic 眼科學 | TFDA-01333 | ISO | ISO 11979-10:2006 | 2006-8-15 | Ophthalmic implants Intraocular lenses Part 10: Phakic intraocular lenses - First Edition | 本標準已改版，請參考新版本標準。(ISO 11979-10:2006 + A1:2014) |
| 560. | 10 Ophthalmic 眼科學 | TFDA-01334 | ISO | ISO 11979-2:1999/Cor 1:2013 | 2003-1-1 | Ophthalmic Implants - Intraocular Lenses - Part 2:Optical Properties and Test Methods - First Edition; Corrigendum 1: 11/1/2003 | 本標準已改版，請參考新版本標準。(ISO 11979-2:2014) |
| 561. | 11 Orthopaedics 骨科學 | TFDA-00080 | ISO | ISO 14630:1997 | 1997-11-01 | Non-active surgical implants -- General requirements | 本標準已改版，請參考新版本標準。(ISO 14630:2012) |
| 562. | 11 Orthopaedics 骨科學 | TFDA-00081 | ISO | ISO 5838-1:1995 | 1995-11-15 | Implants for surgery -- Skeletal pins and wires -- Part 1: Material and mechanical requirements | 本標準已改版，請參考新版本標準。(ISO 5838-1:2013) |
| 563. | 11 Orthopaedics 骨科學 | TFDA-00084 | ISO | ISO 7207-1:1994 | 1994-11-15 | Implants for surgery - Components for partial and total knee joint prostheses - Part 1: Classification, definitions and designation of dimensions | 本標準已改版，請參考新版本標準。(ISO 7207-1:2007 ) |

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| 564. | 11 Orthopaedics 骨科學 | TFDA-00085 | ISO | ISO 7207-2:1998 | 1998-07-15 | Implants for surgery - Components for partial and total knee joint prostheses - Part 2: Articulating surfaces made of metal, ceramic and plastics materials | 本標準已改版，請參考新版本標準。(ISO 7207-2/Amd1:2016) |
| 565. | 11 Orthopaedics 骨科學 | TFDA-00400 | ISO | ISO 14243-1: 2002 | 2002-03-15 | Implants for surgery -- Wear of total knee-joint prostheses -- Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test | 本標準已改版，請參考新版本標準。(ISO 14243-1:2009 ) |
| 566. | 11 Orthopaedics 骨科學 | TFDA-00401 | ISO | ISO 14243-2: 2000 | 2000-10-15 | Implants for surgery -- Wear of total knee-joint prostheses -- Part 2: Methods of measurement | 本標準已改版，請參考新版本標準。(ISO 14243-2:2016) |
| 567. | 11 Orthopaedics 骨科學 | TFDA-00402 | ISO | ISO 14243-3: 2004/Cor 1: 2006 | 2006/02/01 | Implants for surgery – Wear of total knee joint prostheses – Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test – Technical Corrigendum 1 | 本標準已改版，請參考新版本標準。(ISO 14243-3: 2014) |

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| 568. | 11 Orthopaedics 骨科學 | TFDA-00403 | ISO | ISO 14602:1998 | 1998-05-15 | Non-active surgical implants — Implants for Osteosynthesis — Particular requirements | 本標準已改版，請參考新版本標準。(ISO 14602:2010 ) |
| 569. | 11 Orthopaedics 骨科學 | TFDA-00404 | ISO | ISO 21535:2002 | 2002-11-01 | Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants | 本標準已改版，請參考新版本標準。(ISO 21535:2009/Amd1:2016) |
| 570. | 11 Orthopaedics 骨科學 | TFDA-00692 | ISO | ISO 14630:2008 | 2008-1-15 | Non-active surgical implants -- General requirements | 本標準已改版，請參考新版本標準。(ISO 14630:2012) |
| 571. | 11 Orthopaedics 骨科學 | TFDA-00693 | ISO | ISO 21535:2007 | 2007-10-1 | Non-active surgical implants -- Joint replacement implants -- Specific requirements for hip-joint replacement implants | 本標準已改版，請參考新版本標準。(ISO 21535:2007 +A1: 2016) |
| 572. | 11 Orthopaedics 骨科學 | TFDA-00886 | ISO | ISO 14243-2:2009 | 2009-11-15 | Implants for surgery -- Wear of total knee-joint prostheses -- Part 2: Methods of measurement | 本標準已改版，請參考新版本標準。(ISO 14243-2:2016) |
| 573. | 11 Orthopaedics 骨科學 | TFDA-01348 | ASTM | ASTM D2990-09 | 2009-9-1 | Standard Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics | 本標準已改版，請參考新版本標準。(ASTM D2990-17) |

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| 574. | 11 Orthopaedics 骨科學 | TFDA-01350 | ASTM | ASTM D790-10 | 2010-4-1 | Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials | 本標準已改版，請參考新版本標準。(ASTM D790-17) |
| 575. | 11 Orthopaedics 骨科學 | TFDA-01353 | ASTM | ASTM F2077-11 | 2011-8-1 | Test Methods For Intervertebral Body Fusion Devices | 本標準已改版，請參考新版本標準。(ASTM F2077-14) |
| 576. | 11 Orthopaedics 骨科學 | TFDA-01357 | ASTM | ASTM F451-08 | 2008-9-1 | Standard Specification for Acrylic Bone Cement | 本標準已改版，請參考新版本標準。(ASTM F451-16) |
| 577. | 11 Orthopaedics 骨科學 | TFDA-01358 | ASTM | ASTM F1717-11 | 2011-7-1 | Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model | 本標準已改版，請參考新版本標準。(ASTM F1717-14) |
| 578. | 11 Orthopaedics 骨科學 | TFDA-01359 | ASTM | ASTM F2193-02 | 2002-6-10 | Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System | 本標準已改版，請參考新版本標準。(ASTM F2193-14) |
| 579. | 11 Orthopaedics 骨科學 | TFDA-01360 | ISO | ISO 14242-1:2012 | 2012-1-15 | Implants for surgery — Wear of total hipjoint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test - Second Edition | 本標準已改版，請參考新版本標準。(ISO 14242-1:2014) |

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| 580. | 11 Orthopaedics 骨科學 | TFDA-01361 | ISO | ISO 14242-2:2000 | 2000-9-15 | Implants for Surgery - Wear of Total Hip-Joint Prostheses - Part 2: Methods of Measurement - First Edition | 本標準已改版，請參考新版本標準。(ISO 14242-2:2016) |
| 581. | 11 Orthopaedics 骨科學 | TFDA-01366 | ISO | ISO 7207-2:2011 | 2011-8-1 | Implants for surgery -- Components for partial and total knee joint prostheses -- Part 2: Articulating surfaces made of metal, ceramic and plastics materials | 本標準已改版，請參考新版本標準。(ISO 7207-2-A1:2016) |
| 582. | 11 Orthopaedics 骨科學 | TFDA-01370 | ASTM | ASTM F1829-98 (R2009). | 2009-1-1 | Standard Test Method for Static Evaluation of Glenoid Locking Mechanism in Shear | 本標準已改版，請參考新版本標準。(ASTM F1829-16) |
| 583. | 11 Orthopaedics 骨科學 | TFDA-01373 | ASTM | ASTM F2091-01 (R2012). | 2001 (R2012) | Standard Specification for Acetabular Prostheses | 本標準已改版，請參考新版本標準。(F2091-15) |
| 584. | 11 Orthopaedics 骨科學 | TFDA-01374 | ASTM | ASTM F2180-02 (R 2011) | 2002 (R2011) | Standard Specification for Metallic Implantable Strands and Cables | 本標準已改版，請參考新版本標準。(ASTM F2180-17) |
| 585. | 11 Orthopaedics 骨科學 | TFDA-01389 | ASTM | ASTM F2887-12 | 2012-12-15 | Standard Specification For Total Elbow Prostheses | 本標準已改版，請參考新版本標準。(ASTM F2887-17) |
| 586. | 12 Physical Medicine 物理醫學科學 | TFDA-00151 | ISO | ISO 7176-1:1999 | 1999/10/01 | Wheelchairs - Part 1: Determination of Static Stability | 本標準已改版，請參考新版本標準。(ISO 7176-1:2014) |
| 587. | 12 Physical Medicine 物理醫學科學 | TFDA-00153 | ISO | ISO 7176-3:2003 | 2003-04-15 | Wheelchairs - Part 3: Determination of Effectiveness of Brakes | 本標準已改版，請參考新版本標準。(ISO 7176-3:2012) |

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| 588. | 12 Physical Medicine 物理醫學科學 | TFDA-00154 | ISO | ISO 7176-4:1997 | 1997-12-15 | Wheelchairs - Part 4: Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range | 本標準已改版，請參考新版本標準。(ISO 7176-4:2008 ) |
| 589. | 12 Physical Medicine 物理醫學科學 | TFDA-00155 | ISO | ISO 7176-5:1986 | 1986-03-01 | Wheelchairs - Part 5: Determination of Overall Dimensions, Mass and Turning Space | 本標準已改版，請參考新版本標準。(ISO 7176-5:2008 ) |
| 590. | 12 Physical Medicine 物理醫學科學 | TFDA-00158 | ISO | ISO 7176-8:1998 | 1998/07/15 | Wheelchairs -- Part 8: Requirements and test methods for static, impact and fatigue strengths | 本標準已改版，請參考新版本標準。(ISO 7176-8:2014) |
| 591. | 12 Physical Medicine 物理醫學科學 | TFDA-00159 | ISO | ISO 7176-9:2001 | 2001-10-15 | Wheelchairs - Part 9: Climatic tests for electric wheelchairs | 本標準已改版，請參考新版本標準。(ISO 7176-9:2009 ) |
| 592. | 12 Physical Medicine 物理醫學科學 | TFDA-00160 | ISO | ISO 7176-10:1988 | 1988-l 1-15 | Wheelchairs - Part 10: Determination of Obstacle-Climbing Ability of Electric Wheelchairs | 本標準已改版，請參考新版本標準。(ISO 7176-10:2008 ) |
| 593. | 12 Physical Medicine 物理醫學科學 | TFDA-00161 | ISO | ISO 7176-11:1992 | 1992-05-01 | Wheelchairs - Part 11: Test Dummies | 本標準已改版，請參考新版本標準。(ISO 7176-11:2012) |
| 594. | 12 Physical Medicine 物理醫學科學 | TFDA-00163 | ISO | ISO 7176-14:1997 | 1997-10-15 | Wheelchairs - Part 14: Power and Control Systems for Electric Wheelchairs - Requirements and Test Methods | 本標準已改版，請參考新版本標準。(ISO 7176-14:2008 ) |

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| 595. | 12 Physical Medicine 物理醫學科學 | TFDA-00165 | ISO | ISO 7176-16: 1997 | 1997-05-01 | Wheelchairs - Part 16: Resistance to Ignition of Upholstered Parts -- Requirements and Test Methods | 本標準已改版，請參考新版本標準。(ISO 7176-16:2012) |
| 596. | 12 Physical Medicine 物理醫學科學 | TFDA-00166 | ISO | ISO 7176-21:2003 | 2003-04-15 | Wheelchairs -- Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters | 本標準已改版，請參考新版本標準。(ISO 7176-21:2009 ) |
| 597. | 12 Physical Medicine 物理醫學科學 | TFDA-00167 | ISO | ISO 7176-22:2000 | 2000/05/15 | Wheelchairs -- Part 22: Set-up procedures | 本標準已改版，請參考新版本標準。(ISO 7176-22:2014) |
| 598. | 12 Physical Medicine 物理醫學科學 | TFDA-00813 | CNS | CNS 14964-3 | 2006/2/24 | 輪椅－第 3 部：煞車效率之測定 | 本標準已改版，請參考新版本標準。(CNS 14964-3 (2015)) |
| 599. | 12 Physical Medicine 物理醫學科學 | TFDA-00818 | CNS | CNS 14964-9 | 2007/10/12 | 輪椅－第 9 部：電動輪椅之耐候測試 | 本標準已改版，請參考新版本標準。(CNS 14964-9 (2014)) |
| 600. | 12 Physical Medicine 物理醫學科學 | TFDA-00820 | CNS | CNS 14964-11 | 2006/2/24 | 輪椅－第 11 部：測試用假人 | 本標準已改版，請參考新版本標準。(CNS 14964-11 (2016)) |
| 601. | 12 Physical Medicine 物理醫學科學 | TFDA-00997 | CNS | CNS 15191 | 2010/05/18 | 木手杖 | 本標準已改版，請參考新版本標準。(CNS 15191 (2012)) |
| 602. | 12 Physical Medicine 物理醫學科學 | TFDA-00998 | CNS | CNS 15192 | 2010/05/18 | 可調式金屬手杖 | 本標準已改版，請參考新版本標準。(CNS 15192 (2013)) |

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| 603. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00090 | IEC | ISO/IEC 12207:1995 | First edition, 1995-08-01, AMENDMENT 1, 2002-05-01 | Information Technology - Software Life Cycle Processes | 本標準已改版，請參考新版本標準。(ISO/IEC 12207:2008 ed2.0) |
| 604. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00091 | IEEE | IEEE 1012:1998 | 1998-03-01 | Standard for Software Verification and Validation | 本標準已改版，請參考新版本標準。(IEEE 1012:2012) |
| 605. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00092 | IEEE | IEEE 1074:1997 | 1997-12-09 | Standard for Developing Software Life Cycle Processes | 本標準已改版，請參考新版本標準。(IEEE 1074-2006) |
| 606. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00344 | CLSI | AUTO3-A | 2000-12-20 | Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard | 本標準已改版，請參考新版本標準。(AUTO03-A2) |
| 607. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00438 | IEC | IEC 62304:2006 - Ed. 1.0 | 2006-05-09 | Medical device software - Software life cycle processes | 本標準已改版，請參考新版本標準。(IEC 62304:2015) |
| 608. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00444 | AAMI | ANSI/AAMI SW68:2001 | 2001-06-05 | Medical device software—Software life cycle processes | 本標準已廢除，請參考新標準。(IEC 62304:2006+A1:2015) |

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| 609. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00479 | IEC | CEI/IEC 61326-2-6:2005 | 2005-12-15 | Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment | 本標準已改版，請參考新版本標準。(IEC 61326-2-6:2012 ed2.0) |
| 610. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00492 | CLSI | AUTO8-P | 2006-12-19 | Protocols to Validate Laboratory Information Systems; Proposed Guideline | 本標準已改版，請參考新版本標準。(AUTO8-A) |
| 611. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00493 | CLSI | AUTO9-P | 2006-12-19 | Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Proposed Standard | 本標準已改版，請參考新版本標準。(AUTO9-A) |
| 612. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00578 | IEC | ISO/IEC 25000-1:2007 | 2007-01-16 | Software engineering - Software product Quality Requirements and Evaluation (SQuaRE) - Planning and management | 本標準已改版，請參考新版本標準。(ISO/IEC 25001:2014) |
| 613. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00587 | IEC | ISO/IEC 25051:2006 | 2006-03-31 | Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Requirements for quality of Commercial Off-The-Shelf (COTS) software product and instructions for testing | 本標準已改版，請參考新版本標準。(ISO/IEC 25001:2014) |

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| 614. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00736 | CLSI | AUTO11-A | 2006/10/31 | IT Security of In Vitro Diagnostic Instruments and Software Systems | 本標準已改版，請參考新版本標準。(CLSI AUTO11-A2) |
| 615. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00901 | IEEE | IEEE 1012-2004 | 2005-1-1 | IEEE Standard for Software Verification and Validation | 本標準已改版，請參考新版本標準。(IEEE 1012:2012) |
| 616. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00902 | IEEE | IEEE 1074-2006 | 2006-1-1 | IEEE Standard for Developing a Software Project Life Cycle Process | 本標準已被廢除，請參考新標準。(ISO/IEC TR 24774) |
| 617. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00903 | IEC | ANSI/AAMI/IEC 62304:2006 | 2006/7/19 | Medical device software - Software life cycle processes | 本標準已改版，請參考新版本標準。(IEC 62304:2015) |
| 618. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-00960 | CNS | CNS 14232 | 1998-08-31 | 醫療資訊通信協定第七層 | 本標準已廢除，請參考新標準。(CNS 14232-1~16) |
| 619. | 13 Software/Informatics 軟體/醫療資訊 | TFDA-01084 | ISO | ISO/IEEE 11073-20601:2010 | 2010-5-1 | IEEE Health informatics--Personal health device communication Part 20601: Application profile-Optimized Exchange Protocol.--Amendment 1 | 本標準已改版，請參考新版本標準。(IEEE 11073-20601:2014) |
| 620. | 14 Radiology 放射學科學 | TFDA-00105 | IEC | ISO 61217:2003 | 2002-03 | Radiotherapy Equipment - Coordinates, movements, and scales | 本標準已改版，請參考新版本標準。(IEC 61217:2011) |

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| 621. | 14 Radiology 放射學科學 | TFDA-00106 | IEC | IEC 60601-2-1:1998, A1:2002 | 1998-06 | Medical Electrical Equipment - Part 2: Particular Requirements for Medical Electron Accelerators in the Range 1 MeV to 50 MeV | 本標準已改版，請參考新版本標準。(IEC 60601-2-1:2014) |
| 622. | 14 Radiology 放射學科學 | TFDA-00107 | IEC | IEC 60601-2-8:1999 | 1999-04 | Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Therapeutic X-ray Equipment Operating in the Range 10 kV to 1 MV | 本標準已改版，請參考新版本標準。(IEC 60601-2-8:2015) |
| 623. | 14 Radiology 放射學科學 | TFDA-00108 | IEC | IEC 60601-2-11:1997 | 1997-08 | Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Gamma Beam Therapy Equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-11:2013) |
| 624. | 14 Radiology 放射學科學 | TFDA-00109 | IEC | IEC 60601-2-28:1993 | 1993-03 | Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis | 本標準已改版，請參考新版本標準。(IEC 60601-2-28 ed2.0:2010) |
| 625. | 14 Radiology 放射學科學 | TFDA-00110 | IEC | IEC 60601-2-29:1999 | 1999-01 | Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Radiotherapy Simulators | 本標準已改版，請參考新版本標準。(IEC 60601-2-29:2008 Edition 3.0) |

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| 626. | 14 Radiology 放射學科學 | TFDA-00111 | IEC | IEC 60601-2-32:1994 | 1994-03 | Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Associated Equipment of X-ray Equipment (1994) | 本標準已廢除，請參考新標準。(IEC 60601-2-63 ed1.0:2012) |
| 627. | 14 Radiology 放射學科學 | TFDA-00112 | IEC | IEC 60601-2-33:2002 | 2002-05 | Medical Electrical Equipment - Part 2-33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis | 本標準已改版，請參考新版本標準。(IEC 60601-2-33:2015) |
| 628. | 14 Radiology 放射學科學 | TFDA-00113 | IEC | IEC 60601-2-37:2001 | 2001-07 | Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-37:2015) |
| 629. | 14 Radiology 放射學科學 | TFDA-00114 | IEC | IEC 60601-2-43 :2000 | 2000-06 | Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures | 本標準已改版，請參考新版本標準。(IEC 60601-2-43 ed2.0 : 2010) |
| 630. | 14 Radiology 放射學科學 | TFDA-00115 | IEC | IEC 60601-2-44 :2002 | 2002-11 | Particular requirements for the safety of X-ray equipment for computed tomography | 本標準已改版，請參考新版本標準。(IEC 60601-2-44+A2 :2016) |

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| 631. | 14 Radiology 放射學科學 | TFDA-00263 | IEC | IEC 60601-2-7:2998 | 1998-04 | Medical Electrical Equipment - Part 2-7: Particular Requirements for the Safety of High-voltage Generators of Diagnostic X-ray Generators (1998) | 本標準已改版，請參考新版本標準。(IEC 60601-2-54:2015) |
| 632. | 14 Radiology 放射學科學 | TFDA-00264 | IEC | IEC 60601-2-9:1996 | 1997-06-15 | Medical electrical equipment - Part 2: Particular requirements for the safety of patient contact dosimeters used in radiotherapy with electrically connected radiation detectors - Ed. 2.0 | 本標準已廢除，請參考新標準。(IEC 60731:2011+A1:2016) |
| 633. | 14 Radiology 放射學科學 | TFDA-00267 | ISO | ISO 2919:1999 | 1999-02-15 | Radiation protection - Sealed radioactive sources - General requirements and classification | 本標準已改版，請參考新版本標準。(ISO 2919:2012) |
| 634. | 14 Radiology 放射學科學 | TFDA-00268 | IEC | IEC 60731:1997 | 1997-12-15 | Medical Electrical Equipment - Dosimeters with Ionization chambers as used in radiotherapy | 本標準已改版，請參考新版本標準。(IEC 60731:2011+A1:2016) |
| 635. | 14 Radiology 放射學科學 | TFDA-00272 | IEC | IEC 60601-2-45:2001 Ed. 2.0 | 2001-07 | Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices | 本標準已改版，請參考新版本標準。(IEC 60601-2-45:2015) |

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| 636. | 14 Radiology 放射學科學 | TFDA-00273 | IEC | IEC 60601-2-22:1995, Ed. 2.0 | 1996-01 | Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-22:2012) |
| 637. | 14 Radiology 放射學科學 | TFDA-00274 | ISO | ISO 11810-1:2005 | 2005/02/15 | Optics and optical Instruments - Lasers and laser-related equipment - Test method for the laser-resistance of surgical drapes and/or patient-protective covers | 本標準已被廢除，請參考新標準。(ISO 11810:2016) |
| 638. | 14 Radiology 放射學科學 | TFDA-00275 | IEC | IEC 61674:1997 | 2002-06 | Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging | 本標準已改版，請參考新版本標準。(IEC 61674:2012) |
| 639. | 14 Radiology 放射學科學 | TFDA-00276 | ISO | ISO 11146:1999 | 2005-01-15 | Lasers and laser-related equipment - Test methods for laser beam parameters - Beam widths, divergence angle and beam propagation factor | 本標準已廢除，請參考新標準。(ISO 11146-1:2005) |
| 640. | 14 Radiology 放射學科學 | TFDA-00277 | ISO | ISO 11254-1:2000 | 2000-06-01 | Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 1: 1-on-1 test | 本標準已廢除，請參考新標準。(ISO 21254-1:2011) |

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| 641. | 14 Radiology 放射學科學 | TFDA-00278 | ISO | ISO 11254-2:2001 | 2001-09-15 | Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 2: S-on-1 test | 本標準已廢除，請參考新標準。(ISO 21254-1:2011) |
| 642. | 14 Radiology 放射學科學 | TFDA-00280 | ISO | ISO 11554:2003 | 2003-04 | Optics and optical instruments - Lasers and laser-related equipment - Test methods for laser beam power, energy and temporal characteristics | 本標準已改版，請參考新版本標準。(ISO 11554:2006) |
| 643. | 14 Radiology 放射學科學 | TFDA-00284 | CNS | CNS 14509-3 | 2001/01/30 | Medical Electrical Equipment--Part 1-3: General Requirements for Safety-Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment (IDE IEC 60601-1-3) | 本標準已被廢除，請參考新標準。(狀態: 廢止; 廢止日期: 105/10/19) |
| 644. | 14 Radiology 放射學科學 | TFDA-00413 | IEC | IEC 61689:1996 | 1996-08-23 | Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz Ed. 1.0 | 本標準已改版，請參考新版本標準。(IEC 61689:2013) |
| 645. | 14 Radiology 放射學科學 | TFDA-00416 | IEC | IEC 60601-2-5:2000 | 2000-7 | Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment Ed. 2.0 | 本標準已改版，請參考新版本標準。(IEC 60601-2-5 ed3.0 : 2009) |

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| 646. | 14 Radiology 放射學科學 | TFDA-00420 | IEEE | IEEE N42.13-1986 | 1986 | Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides | 本標準已改版，請參考新版本標準。(IEEE N42.13, 2004) |
| 647. | 14 Radiology 放射學科學 | TFDA-00423 | IEC | IEC 60825-1 - Consol. Ed. 1.2 (incl. am1+am2) | 2001-08-30 | Safety of laser products - Part 1: Equipment classification, requirements and user's guide | 本標準已改版，請參考新版本標準。(IEC 60825-1:2014 ed3.0) |
| 648. | 14 Radiology 放射學科學 | TFDA-00424 | IEC | IEC 60825-2 - Ed. 3.0 | 2004-06 | Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS) | 本標準已改版，請參考新版本標準。(IEC 60825-2:2010) |
| 649. | 14 Radiology 放射學科學 | TFDA-00425 | IEC | IEC/TR 60825-3 - Ed. 1.0 | 1995-12-18 | Safety of laser products - Part 3: Guidance for laser displays and shows | 本標準已改版，請參考新版本標準。(IEC/TR 60825-3:2008 Ed.2.0) |
| 650. | 14 Radiology 放射學科學 | TFDA-00426 | IEC | IEC 60825-4 - Consol. Ed. 1.2 (incl. am1+am2) | 2003-10 | Safety of laser products - Part 4: Laser guards | 本標準已改版，請參考新版本標準。(IEC 60825-4:2011) |
| 651. | 14 Radiology 放射學科學 | TFDA-00428 | IEC | IEC/TR 60825-8 - Ed. 1.0 | 1999-11-25 | Safety of laser products - Part 8: Guidelines for the safe use of medical laser equipment | 本標準已改版，請參考新版本標準。(IEC/TR 60825-8:2006) |
| 652. | 14 Radiology 放射學科學 | TFDA-00429 | IEC | IEC/TR 60825-9 - Ed. 1.0 | 1999-10-29 | Safety of laser products - Part 9: Compilation of maximum permissible exposure to incoherent optical radiation | 本標準已廢除，請參考新標準。(IEC 60825-1:2014 ed3.0) |

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| 653. | 14 Radiology 放射學科學 | TFDA-00430 | IEC | IEC/TR 60825-10 - Ed. 1.0 | 2002-02-22 | Safety of laser products - Part 10: Application guidelines and explanatory notes to IEC 60825-1 | 本標準已廢除，請參考新標準。(IEC 60825-1:2014 ed3.0) |
| 654. | 14 Radiology 放射學科學 | TFDA-00582 | IEC | IEC 60601-2-45 :2001 | 2001-05-01 | Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices | 本標準已改版，請參考新版本標準。(IEC 60601-2-45:2015) |
| 655. | 14 Radiology 放射學科學 | TFDA-00697 | IEC | IEC 60601-1-3 Edition 2.0 (2008-01) | 2008-1-12 | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment | 本標準已改版，請參考新版本標準。(IEC 60601-1-3:2013) |
| 656. | 14 Radiology 放射學科學 | TFDA-00698 | IEC | IEC 60601-2-33 Consolidated Edition 2.2 (incl. am1+am2) (2008-04) | 2008-4-14 | Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis | 本標準已改版，請參考新版本標準。(IEC 60601-2-33:2015) |
| 657. | 14 Radiology 放射學科學 | TFDA-00699 | IEC | IEC 60601-2-37:2007 Edition 2.0 | 2007-8-9 | Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-37:2015) |

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| 658. | 14 Radiology 放射學科學 | TFDA-00700 | IEC | IEC 60825-1 Edition 2.0 (2007-03) | 2007-3-30 | Safety of laser products - Part 1: Equipment classification and requirements | 本標準已改版，請參考新版本標準。(IEC 60825-1:2014 ed3.0) |
| 659. | 14 Radiology 放射學科學 | TFDA-00701 | IEC | IEC 61217 Consolidated Edition 1.2 (incl. am1+am2) (2008-04) | 2008-4-14 | Radiotherapy equipment - Coordinates, movements and scales | 本標準已改版，請參考新版本標準。(IEC 61217:2011) |
| 660. | 14 Radiology 放射學科學 | TFDA-00702 | IEC | IEC 61689 Edition 2.0 (2007-08) | 2007-8-9 | Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz | 本標準已改版，請參考新版本標準。(IEC 61689:2013) |
| 661. | 14 Radiology 放射學科學 | TFDA-00728 | IEC | IEC 60601-2-22 Edition 3.0 (2007-05) | 2007-5-23 | Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-22:2012) |
| 662. | 14 Radiology 放射學科學 | TFDA-00729 | IEC | IEC 60601-2-11-am1 Edition 2.0 (2004-07) | 2004-7-15 | Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-11:2013) |
| 663. | 14 Radiology 放射學科學 | TFDA-00748 | CNS | CNS 14176-1 | 2005-2-25 | 醫學數位影像及通信－第 1 部：簡介與概述 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 664. | 14 Radiology 放射學科學 | TFDA-00749 | CNS | CNS 14176-2 | 2005-5-13 | 醫學數位影像及通信－第 2 部：符合性 | 本標準已廢除，請參考新標準。(CNS 15211) |

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| 665. | 14 Radiology 放射學科學 | TFDA-00750 | CNS | CNS 14176-3 | 1998-8-11 | 醫學數位影像及通信－第 3 部：資訊物件定義 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 666. | 14 Radiology 放射學科學 | TFDA-00751 | CNS | CNS 14176-4 | 1998-8-11 | 醫學數位影像及通信－第 4 部：服務類別規格 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 667. | 14 Radiology 放射學科學 | TFDA-00752 | CNS | CNS 14176-5 | 1998-8-11 | 醫學數位影像及通信－第 5 部：資料結構及編碼 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 668. | 14 Radiology 放射學科學 | TFDA-00753 | CNS | CNS 14176-6 | 2005-2-5 | 醫學數位影像及通信－第 6 部：資料辭典 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 669. | 14 Radiology 放射學科學 | TFDA-00754 | CNS | CNS 14176-7 | 1998-6-25 | 醫學數位影像及通信－第 7 部：訊息交換 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 670. | 14 Radiology 放射學科學 | TFDA-00755 | CNS | CNS 14176-8 | 2005-5-13 | 醫學數位影像及通信－第 8 部：訊息交換之網路通信支援 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 671. | 14 Radiology 放射學科學 | TFDA-00756 | CNS | CNS 14176-9 | 1998-6-25 | 醫學數位影像及通信－第 9 部：訊息交換之點對點通信支援 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 672. | 14 Radiology 放射學科學 | TFDA-00757 | CNS | CNS 14176-10 | 2007-8-21 | 醫學數位影像及通信－第 10 部：媒體交換之媒體儲存與檔案格式 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 673. | 14 Radiology 放射學科學 | TFDA-00758 | CNS | CNS 14176-11 | 2007-8-21 | 醫學數位影像及通信－第 11 部：媒體儲存應用規範 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 674. | 14 Radiology 放射學科學 | TFDA-00759 | CNS | CNS 14176-12 | 2007-8-21 | 醫學數位影像及通信－第 12 部：媒體交換之媒體格式與實體媒體 | 本標準已廢除，請參考新標準。(CNS 15211) |

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| 675. | 14 Radiology 放射學科學 | TFDA-00760 | CNS | CNS 14176-14 | 2007-8-21 | 醫學數位影像及通信－第 14 部：灰階標準顯示函數 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 676. | 14 Radiology 放射學科學 | TFDA-00761 | CNS | CNS 14176-15 | 2007-8-21 | 醫學數位影像及通信－第 15 部：安全規範 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 677. | 14 Radiology 放射學科學 | TFDA-00762 | CNS | CNS 14176-18 | 2008-12-26 | 醫學數位影像及通信－第 18 部：DICOM 永續物件之資訊網存取 | 本標準已廢除，請參考新標準。(CNS 15211) |
| 678. | 14 Radiology 放射學科學 | TFDA-00763 | NEMA | NEMA PS 3.1-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview | 本標準已改版，請參考新版本標準。(NEMA PS 3.1-2011) |
| 679. | 14 Radiology 放射學科學 | TFDA-00764 | NEMA | NEMA PS 3.2-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 2: Conformance | 本標準已改版，請參考新版本標準。(NEMA PS 3.2-2011) |
| 680. | 14 Radiology 放射學科學 | TFDA-00765 | NEMA | NEMA PS 3.3-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions | 本標準已改版，請參考新版本標準。(NEMA PS 3.3-2011) |
| 681. | 14 Radiology 放射學科學 | TFDA-00766 | NEMA | NEMA PS 3.4-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications | 本標準已改版，請參考新版本標準。(NEMA PS 3.4-2011) |
| 682. | 14 Radiology 放射學科學 | TFDA-00767 | NEMA | NEMA PS 3.5-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding | 本標準已改版，請參考新版本標準。(NEMA PS 3.5-2011) |

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| 683. | 14 Radiology 放射學科學 | TFDA-00768 | NEMA | NEMA PS 3.6-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 6: Data Dictionary | 本標準已改版，請參考新版本標準。(NEMA PS 3.6-2011) |
| 684. | 14 Radiology 放射學科學 | TFDA-00769 | NEMA | NEMA PS 3.7-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 7: Message Exchange | 本標準已改版，請參考新版本標準。(NEMA PS 3.7-2011) |
| 685. | 14 Radiology 放射學科學 | TFDA-00770 | NEMA | NEMA PS 3.8-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange | 本標準已改版，請參考新版本標準。(NEMA PS 3.8-2011) |
| 686. | 14 Radiology 放射學科學 | TFDA-00771 | NEMA | NEMA PS 3.10-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for Media Interchange | 本標準已改版，請參考新版本標準。(NEMA PS 3.10-2011) |
| 687. | 14 Radiology 放射學科學 | TFDA-00772 | NEMA | NEMA PS 3.11-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles | 本標準已改版，請參考新版本標準。(NEMA PS 3.11-2011) |
| 688. | 14 Radiology 放射學科學 | TFDA-00773 | NEMA | NEMA PS 3.12-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange | 本標準已改版，請參考新版本標準。(NEMA PS 3.12-2011) |

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| 689. | 14 Radiology 放射學科學 | TFDA-00774 | NEMA | NEMA PS 3.14-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function | 本標準已改版，請參考新版本標準。(NEMA PS 3.14-2011) |
| 690. | 14 Radiology 放射學科學 | TFDA-00775 | NEMA | NEMA PS 3.15-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 15: Security and System Management Profiles | 本標準已改版，請參考新版本標準。(NEMA PS 3.15-2011) |
| 691. | 14 Radiology 放射學科學 | TFDA-00776 | NEMA | NEMA PS 3.16-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource | 本標準已改版，請參考新版本標準。(NEMA PS 3.16-2011) |
| 692. | 14 Radiology 放射學科學 | TFDA-00777 | NEMA | NEMA PS 3.17-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 17: Explanatory Information | 本標準已改版，請參考新版本標準。(NEMA PS 3.17-2011) |
| 693. | 14 Radiology 放射學科學 | TFDA-00778 | NEMA | NEMA PS 3.18-2008 | 2008-1-23 | Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Access to DICOM Persistent Objects (WADO) | 本標準已改版，請參考新版本標準。(NEMA PS 3.18-2011) |
| 694. | 14 Radiology 放射學科學 | TFDA-00891 | IEC | IEC 60601-2-1 ed3.0 : 2009 | 2009-10-13 | Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV | 本標準已改版，請參考新版本標準。(IEC 60601-2-1:2014) |

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| 695. | 14 Radiology 放射學科學 | TFDA-00894 | IEC | IEC 60601-2-44 ed3.0 : 2009 | 2009-2-25 | Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography | 本標準已改版，請參考新版本標準。(IEC 60601-2-44+A2 :2016) |
| 696. | 14 Radiology 放射學科學 | TFDA-00895 | IEC | IEC 60731-am1 ed2.0 : 2002 | 2002-6-5 | Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy, Amendment 1 | 本標準已改版，請參考新版本標準。(IEC 60731:2011+A1:2016) |
| 697. | 14 Radiology 放射學科學 | TFDA-00897 | IEC | IEC 60825-2 ed3.1 Consol. with am1 | 2007-1-30 | Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS) | 本標準已改版，請參考新版本標準。(IEC 60825-2:2010) |
| 698. | 14 Radiology 放射學科學 | TFDA-00899 | IEC | IEC 60825-4 ed2.1 Consol. with am1 : 2009 | 2009-10-28 | Safety of laser products - Part 4: Laser guards | 本標準已改版，請參考新版本標準。(IEC 60825-4:2011) |
| 699. | 14 Radiology 放射學科學 | TFDA-01396 | IEC | IEC 60601-2-33:2013 | 2013-4-23 | Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis - Edition 3.1; Consolidated Reprint | 本標準已改版，請參考新版本標準。(IEC 60601-2-33:2015) |

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| 700. | 14 Radiology 放射學科學 | TFDA-01397 | IEC | IEC 60601-2-44:2012 | 2012-9-18 | Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography - Edition 3.1; Consolidated Reprint | 本標準已改版，請參考新版本標準。(IEC 60601-2-44 + A2:2016) |
| 701. | 14 Radiology 放射學科學 | TFDA-01398 | IEC | IEC 60601-2-45:2011 | 2011-2-10 | Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices - Edition 3.0 | 本標準已改版，請參考新版本標準。(IEC 60601-2-45:2015) |
| 702. | 14 Radiology 放射學科學 | TFDA-01399 | IEC | IEC 60601-2-54:2009+Corr1:2010 | 2009-6-29 | Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy CORRIGENDUM 1 - Edition 1.0 | 本標準已改版，請參考新版本標準。(IEC 60601-2-54:2015) |
| 703. | 14 Radiology 放射學科學 | TFDA-01403 | IEC | IEC 60601-2-8:2010 ed2.0 | 2010-11-10 | Medical electrical equipment - Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV | 本標準已改版，請參考新版本標準。(IEC 60601-2-8:2015) |

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| 704. | 14 Radiology 放射學科學 | TFDA-01405 | IEC | IEC 60731:2011 | 2011-2-25 | Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy - Edition 3.0 | 本標準已改版，請參考新版本標準。(IEC 60731:2011+A1:2016) |
| 705. | 14 Radiology 放射學科學 | TFDA-01414 | IEC | IEC 61223-3-5:2004 | 2004-8-1 | Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment - Edition 1.0 | 本標準已改版，請參考新版本標準。(IEC 61223-3-5:2004+CORR1:2006) |
| 706. | 14 Radiology 放射學科學 | TFDA-01422 | IEC | IEC 62127-2:2007+A1:2013 | 2013-2-1 | Ultrasonics—Hydrophones—Part 2: Calibration for ultrasonic fields up to 40 MHz (including corrigendum 1:2008 and amendment 1:2013). | 本標準已改版，請參考新版本標準。(IEC 62127-2:2007+A1:2013+A2:2017) |
| 707. | 14 Radiology 放射學科學 | TFDA-01433 | ISO | ISO/ASTM 51707:2005 | 2005-5-15 | Guide for estimating uncertainties in dosimetry for radiation processing | 本標準已改版，請參考新版本標準。(ISO/ASTM 51707-15) |
| 708. | 14 Radiology 放射學科學 | TFDA-01434 | NEMA | NEMA PS 3.10-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for Media Interchange | 本標準已改版，請參考新版本標準。(DICOM PS3.10 2016e) |
| 709. | 14 Radiology 放射學科學 | TFDA-01435 | NEMA | NEMA PS 3.11-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles | 本標準已改版，請參考新版本標準。(DICOM PS3.11 2016e) |

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| 710. | 14 Radiology 放射學科學 | TFDA-01436 | NEMA | NEMA PS 3.1-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview | 本標準已改版，請參考新版本標準。(DICOM PS3.1 2016e) |
| 711. | 14 Radiology 放射學科學 | TFDA-01437 | NEMA | NEMA PS 3.12-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange | 本標準已改版，請參考新版本標準。(DICOM PS3.12 2016e) |
| 712. | 14 Radiology 放射學科學 | TFDA-01438 | NEMA | NEMA PS 3.14-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function | 本標準已改版，請參考新版本標準。(DICOM PS3.14 2016e) |
| 713. | 14 Radiology 放射學科學 | TFDA-01439 | NEMA | NEMA PS 3.15-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 15: Security and System Management Profiles | 本標準已改版，請參考新版本標準。(DICOM PS3.15 2016e) |
| 714. | 14 Radiology 放射學科學 | TFDA-01440 | NEMA | NEMA PS 3.16-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource | 本標準已改版，請參考新版本標準。(DICOM PS3.16 2016e) |
| 715. | 14 Radiology 放射學科學 | TFDA-01441 | NEMA | NEMA PS 3.17-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 17: Explanatory Information | 本標準已改版，請參考新版本標準。(DICOM PS3.17 2016e) |
| 716. | 14 Radiology 放射學科學 | TFDA-01442 | NEMA | NEMA PS 3.18-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Access to DICOM Persistent Objects (WADO) | 本標準已改版，請參考新版本標準。(DICOM PS3.18 2016e) |

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| 717. | 14 Radiology 放射學科學 | TFDA-01443 | NEMA | NEMA PS 3.19-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 19: Application Hosting | 本標準已改版，請參考新版本標準。(DICOM PS3.19 2016e) |
| 718. | 14 Radiology 放射學科學 | TFDA-01444 | NEMA | NEMA PS 3.20-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 20: Transformation of DICOM to and from HL7 Standards | 本標準已改版，請參考新版本標準。(DICOM PS3.20 2016e) |
| 719. | 14 Radiology 放射學科學 | TFDA-01445 | NEMA | NEMA PS 3.2-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 2: Conformance | 本標準已改版，請參考新版本標準。(DICOM PS3.2 2016e) |
| 720. | 14 Radiology 放射學科學 | TFDA-01446 | NEMA | NEMA PS 3.3-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions | 本標準已改版，請參考新版本標準。(DICOM PS3.3 2016e) |
| 721. | 14 Radiology 放射學科學 | TFDA-01447 | NEMA | NEMA PS 3.4-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications | 本標準已改版，請參考新版本標準。(DICOM PS3.4 2016e) |
| 722. | 14 Radiology 放射學科學 | TFDA-01448 | NEMA | NEMA PS 3.5-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding | 本標準已改版，請參考新版本標準。(DICOM PS3.5 2016e) |
| 723. | 14 Radiology 放射學科學 | TFDA-01449 | NEMA | NEMA PS 3.6-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 6: Data | 本標準已改版，請參考新版本標準。(DICOM PS3.6 |

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| | | | | | | Dictionary | 2016e) |
| 724. | 14 Radiology 放射學科學 | TFDA-01450 | NEMA | NEMA PS 3.7-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 7: Message Exchange | 本標準已改版，請參考新版本標準。(DICOM PS3.7 2016e) |
| 725. | 14 Radiology 放射學科學 | TFDA-01451 | NEMA | NEMA PS 3.8-2011 | 2011-8-10 | Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange | 本標準已改版，請參考新版本標準。(DICOM PS3.8 2016e) |
| 726. | 15 Sterility 滅菌 | TFDA-00013 | ISO | ISO 11134：1994 | 1994-02-01 | Sterilization of health care products - Requirements for validation and routine control-industrial moist heat sterilization. | 本標準已廢除，請參考新標準。(ISO 17665-1:2006) |
| 727. | 15 Sterility 滅菌 | TFDA-00014 | ISO | ISO 11135：1994 | 1994-11-15 | Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. | 本標準已廢除，請參考新標準。(ISO 11135:2014) |
| 728. | 15 Sterility 滅菌 | TFDA-00015 | ISO | ISO 11137：1995, Amendment 1：2001 | 1995-03-01, Amendment 2001-12-15 | Sterilization of Health Care Products - Requirements for Validation and Routine Control-Radiation Sterilization and Amendment 1 | 本標準已廢除，請參考新標準。(ISO 11137-1 :2015) |
| 729. | 15 Sterility 滅菌 | TFDA-00025 | ISO | ISO 11607:2000 | 2003-02-15 | Packaging for terminally sterilized medical devices | 本標準已廢除，請參考新標準。(ISO |

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| 730. | 15 Sterility 滅菌 | TFDA-00026 | ISO | ISO 11737-1:1995 | 1995-12-01 | Sterilization of medical devices-microbiological methods-Part 1: Estimation of the population of microorganisms on product. | 本標準已改版，請參考新版本標準。(ISO 11737-1:2006) |
| 731. | 15 Sterility 滅菌 | TFDA-00028 | ISO | ISO 13408-1:1998 | 1998-08-01 | Aseptic processing of health care products -- Part 1: General requirements | 本標準已改版，請參考新版本標準。(ISO 13408-1:2015) |
| 732. | 15 Sterility 滅菌 | TFDA-00030 | ISO | ISO 14160:1998 | 1998-03-15 | Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants | 本標準已改版，請參考新版本標準。(ISO 14160:2011) |
| 733. | 15 Sterility 滅菌 | TFDA-00031 | ISO | ISO 14161:2000 | 2000-10-01 | Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results, 2ed. | 本標準已改版，請參考新版本標準。(ISO 14161:2009 ) |
| 734. | 15 Sterility 滅菌 | TFDA-00032 | ISO | ISO 14644-1:1999 | 1999-5-1 | Cleanrooms and Associated Conrtolled Environments - Part 1: Classification of Air Cleanliness | 本標準已改版，請參考新版本標準。(ISO 14644-1:2015) |
| 735. | 15 Sterility 滅菌 | TFDA-00033 | ISO | ISO 14644-2:2000 | 2000-9-15 | Cleanrooms and Associated Controlled Environments - Part 2: | 本標準已改版，請參考新版本標準。(ISO 14644-2:2015) |

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| | | | | | | Specification for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1 | |
| 736. | 15 Sterility 滅菌 | TFDA-00037 | ISO | ISO 14937:2000 | 2003-06-01 | Sterilization of Health Care Products - General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices | 本標準已改版，請參考新版本標準。(ISO 14937:2009 ) |
| 737. | 15 Sterility 滅菌 | TFDA-00225 | AAMI | AAMI ST8:2001 | 1994-01-04 | Hospital Steam Sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST8:2013 ) |
| 738. | 15 Sterility 滅菌 | TFDA-00226 | AOAC | 6.2.02:2005 | 2005 | Official Method 991.47, Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method | 本標準已改版，請參考新版本標準。(6.2.02:2012) |
| 739. | 15 Sterility 滅菌 | TFDA-00227 | AOAC | 6.2.03:2005 | 2005 | Official Method 991.48, Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method | 本標準已改版，請參考新版本標準。(6.2.03:2012) |
| 740. | 15 Sterility 滅菌 | TFDA-00228 | AOAC | 6.2.05:2005 | 2005 | Official Method 991.49, Testing Disinfectants Against Pseudomonas aeruginosa,Hard Surface Carrier Test Method | 本標準已改版，請參考新版本標準。(6.2.05:2012) |

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| 741. | 15 Sterility 滅菌 | TFDA-00229 | AOAC | 6.3.02:2005 | 2005 | Official Method 955.17, Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes | 本標準已改版，請參考新版本標準。(6.3.02:2012) |
| 742. | 15 Sterility 滅菌 | TFDA-00230 | AOAC | 6.3.05:2005 | 2005 | Official Method 966.04, Sporicidal Activity of Disinfectants | 本標準已改版，請參考新版本標準。(6.3.05:2012) |
| 743. | 15 Sterility 滅菌 | TFDA-00231 | AOAC | 6.3.06:2005 | 2005 | Official Method 965.12, Tuberculocidal Activity of Disinfectants | 本標準已改版，請參考新版本標準。(6.3.06:2012) |
| 744. | 15 Sterility 滅菌 | TFDA-00232 | AAMI | AAMI ST50:2004 | 2004-04-07 | Dry heat (heated air) sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST50:2004/(R)2010) |
| 745. | 15 Sterility 滅菌 | TFDA-00349 | ISO | ISO11607-1:2006 | 2006-4-15 | Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems | 本標準已改版，請參考新版本標準。(ISO 11607-1:2009 AMD 1:2014) |
| 746. | 15 Sterility 滅菌 | TFDA-00350 | ISO | ISO11607-2:2006 | 2006-4-15 | Packaging for terminally sterilized medical devices —Part 2:Validation requirements for forming, sealing and assembly processes | 本標準已改版，請參考新版本標準。(ISO 11607-2 AMD 1:2014) |
| 747. | 15 Sterility 滅菌 | TFDA-00356 | ISO | ISO11137-1:2006 | 2006-03-12 | Sterilization of health care products —Radiation —Part 1: Requirements for development, validation and routine control of a | 本標準已改版，請參考新版本標準。(ISO 11137-1 :2015) |

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| | | | | | | sterilization process for medical devices | |
| 748. | 15 Sterility 滅菌 | TFDA-00357 | ISO | ISO11137-2:2006 | 2006-03-12 | Sterilization of health care products —Radiation —Part 2: Establishing the sterilization dose | 本標準已改版，請參考新版本標準。(ISO 11137-2:2015) |
| 749. | 15 Sterility 滅菌 | TFDA-00360 | CEN | EN 556-1:2001 | 2001-08-18 | Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices | 本標準已改版，請參考新版本標準。(EN 556-1:2001/AC:2006) |
| 750. | 15 Sterility 滅菌 | TFDA-00513 | ISO | ISO 11140-1:2005 | 2005/7/15 | Sterilization of health care products -- Chemical indicators -- Part 1: General requirements | 本標準已改版，請參考新版本標準。(ISO 11140-1:2014) |
| 751. | 15 Sterility 滅菌 | TFDA-00519 | ISO | ISO 11138-1:2006 | 2006/07/01 | Sterilization of health care products -- Biological indicators -- Part 1: General requirements | 本標準已改版，請參考新版本標準。(ISO 11138-1:2017) |
| 752. | 15 Sterility 滅菌 | TFDA-00520 | ISO | ISO 11138-2:2006 | 2006/07/01 | Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes | 本標準已改版，請參考新版本標準。(ISO 11138-2:2017) |
| 753. | 15 Sterility 滅菌 | TFDA-00521 | ISO | ISO 11138-3:2006 | 2006/06/26 | Sterilization of health care products -- Biological indicators -- Part 3: Biological indicators for moist heat sterilization processes | 本標準已改版，請參考新版本標準。(ISO 11138-3:2017) |

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| 754. | 15 Sterility 滅菌 | TFDA-00522 | ISO | ISO 11138-4:2006 | 2006/7/1 | Sterilization of health care products -- Biological indicators -- Part 4: Biological indicators for dry heat sterilization processes | 本標準已改版，請參考新版本標準。(ISO 11138-4:2017) |
| 755. | 15 Sterility 滅菌 | TFDA-00523 | ISO | ISO 11138-5:2006 | 20067/1 | Sterilization of health care products -- Biological indicators -- Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes | 本標準已改版，請參考新版本標準。(ISO 11138-5:2017) |
| 756. | 15 Sterility 滅菌 | TFDA-00528 | ISO | ISO 11737-2:1998 | 1998-07-09 | Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the validation of a sterilization process | 本標準已改版，請參考新版本標準。(ISO 11737-2:2009 ) |
| 757. | 15 Sterility 滅菌 | TFDA-00531 | ISO | ISO 13408-6:2005 | 2005-06-15 | Aseptic processing of health care products -- Part 6: Isolator systems | 本標準已改版，請參考新版本標準。(ISO 13408-6:2005/Amd 1:2013) |
| 758. | 15 Sterility 滅菌 | TFDA-00532 | ISO | ISO 14644-8:2006 | 2006-8-15 | Cleanrooms and associated controlled environments -- Part 8: Classification of airborne molecular contamination | 本標準已改版，請參考新版本標準。(ISO 14644-8:2013) |
| 759. | 15 Sterility 滅菌 | TFDA-00534 | AAMI | ST24:1999 | 2000-02-07 | Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities | 本標準已改版，請參考新版本標準。(AAMI ST24:1999/(R)2009) |

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| 760. | 15 Sterility 滅菌 | TFDA-00535 | AAMI | ST55:2003 | 2004-6-2 | Table-top steam sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST55:2010) |
| 761. | 15 Sterility 滅菌 | TFDA-00536 | AAMI | ST66:1999 | 1999-10-01 | Sterilization of health care products Chemical indicators Part 2: Class 2 indicators for air removal test sheets and packs | 本標準已廢除，請參考新標準。(ISO 11140-5:2007) |
| 762. | 15 Sterility 滅菌 | TFDA-00537 | AAMI | ST77:2006 | 2007-01-16 | Containment devices, reusable rigid sterilization containers, instrument cases, cassettes, organizing trays | 本標準已改版，請參考新版本標準。(AAMI ST77:2013 ) |
| 763. | 15 Sterility 滅菌 | TFDA-00538 | ISO | ISO 15882:2003 | 2003-03-15 | Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results | 本標準已改版，請參考新版本標準。(ISO 15882:2008) |
| 764. | 15 Sterility 滅菌 | TFDA-00669 | AAMI | ASTM ST24:1999/(R)2005 | 2009-4-13 | Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities | 本標準已改版，請參考新版本標準。(AAMI ST24:1999/(R)2009) |
| 765. | 15 Sterility 滅菌 | TFDA-00670 | AOAC | AOAC 6.2.02:2007 | 2007 | Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method | 本標準已改版，請參考新版本標準。(6.2.02:2012) |
| 766. | 15 Sterility 滅菌 | TFDA-00671 | AOAC | AOAC 6.2.03:2007 | 2007 | Testing Disinfectants Against Staphylococcus aureus, Hard Surface | 本標準已改版，請參考新版本標準。(6.2.03:2012) |

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| 767. | 15 Sterility 滅菌 | TFDA-00672 | AOAC | AOAC 6.2.05:2007 | 2007 | Testing Disinfectants Against Pseudomonas aeruginosa,Hard Surface Carrier Test Method. | 本標準已改版，請參考新版本標準。(6.2.05:2012) |
| 768. | 15 Sterility 滅菌 | TFDA-00673 | AOAC | AOAC 6.3.02:2007 | 2007 | Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes. | 本標準已改版，請參考新版本標準。(6.3.02:2012) |
| 769. | 15 Sterility 滅菌 | TFDA-00674 | AOAC | AOAC 6.3.05:2007 | 2007 | Sporicidal Activity of Disinfectants Method I. | 本標準已改版，請參考新版本標準。(6.3.05:2012) |
| 770. | 15 Sterility 滅菌 | TFDA-00675 | AOAC | AOAC 6.3.06:2007 | 2007 | Tuberculocidal Activity of Disinfectants. | 本標準已改版，請參考新版本標準。(6.3.06:2012) |
| 771. | 15 Sterility 滅菌 | TFDA-00678 | ISO | ISO 11135-1:2007 | 2007/5/1 | Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices | 本標準已被廢除，請參考新標準。(ISO 11135:2014) |
| 772. | 15 Sterility 滅菌 | TFDA-00679 | ISO | ISO/TS 11135-2:2008 | 2008-8-1 | Sterilization of health care products -- Ethylene oxide -- Part 2: Guidance on the application of ISO 11135-1 | 本標準已被廢除，請參考新標準。(ISO 11135:2014) |
| 773. | 15 Sterility 滅菌 | TFDA-00863 | ISO | ISO 13408-1:2008 | 2008-6-15 | Aseptic processing of health care products -- Part 1: General requirements | 本標準已改版，請參考新版本標準。(ISO 13408-1:2015) |

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| 774. | 15 Sterility 滅菌 | TFDA-00866 | AAMI | ST8:2008 | 2009-3-24 | Hospital steam sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST8:2013 ) |
| 775. | 15 Sterility 滅菌 | TFDA-00869 | AAMI | ST55:2003/(R)2008 | 2008-12-15 | Table-top steam sterilizers | 本標準已改版，請參考新版本標準。(AAMI ST55:2010) |
| 776. | 15 Sterility 滅菌 | TFDA-01044 | ISO | ISO 11137-1:2006/Amd 1:2013 | 2013-7-15 | Sterilization of health care products —Radiation —Part 1:Requirements for development, validation and routine control of a sterilization process for medical devices | 本標準已改版，請參考新版本標準。(ISO 11137-1 :2015) |
| 777. | 15 Sterility 滅菌 | TFDA-01045 | ISO | ISO 11137-2:2013 | 2013-6-1 | Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose | 本標準已改版，請參考新版本標準。(ISO 11137-2 :2015) |
| 778. | 15 Sterility 滅菌 | TFDA-01046 | ISO | ISO 13408-1:2008/Amd 1:2013 | 2013-5-1 | Aseptic processing of health care products -- Part 1:General requirements | 本標準已改版，請參考新版本標準。(ISO 13408-1:2015) |
| 779. | 15 Tissue Engineering 組織工程 | TFDA-00737 | ASTM | F2347-03 | 2003-12 | Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications | 本標準已改版，請參考新版本標準。(ASTM F2347-15) |
| 780. | 15 Tissue Engineering 組織工程 | TFDA-00738 | ASTM | F2450-04 | 2004-12 | Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue | 本標準已改版，請參考新版本標準。(ASTM F2450-10) |

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| 781. | 15 Tissue Engineering 組織工程 | TFDA-00740 | ASTM | F2315-03 | 2003-10 | Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels | 本標準已改版，請參考新版本標準。(ASTM F2315-11) |
| 782. | 15 Tissue Engineering 組織工程 | TFDA-00742 | ASTM | F2451-05 | 2005-5 | Standard Guide for in vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage | 本標準已改版，請參考新版本標準。(ASTM F2451-05/(R)2010) |
| 783. | 15 Tissue Engineering 組織工程 | TFDA-00948 | ASTM | ASTM F2603-06 | 2007-2 | Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds | 本標準已改版，請參考新版本標準。(ASTM F2603-06/(R)2012) |
| 784. | 16 Tissue Engineering 組織工程 | TFDA-00739 | ASTM | F2064-00(2006) | 2000 (R2006) | Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Products Application | 本標準已改版，請參考新版本標準。(ASTM F2064-14) |
| 785. | 16 Tissue Engineering 組織工程 | TFDA-01102 | ASTM | ASTM F2347-11 | 2011-3-1 | Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications | 本標準已改版，請參考新版本標準。(ASTM F2347 - 15) |
| 786. | 17 Neurology 神經學 | TFDA-00116 | IEC | IEC 60601-2-10 :1987 | 2001-06 | Medical electrical equipment - Part 2: Particular requirements for the safety | 本標準已改版，請參考新版本標準。(IEC |

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| 787. | 17 Neurology 神經學 | TFDA-00606 | ASTM | ASTM F647–94 (R2000) | 1994-08-01 | Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application | 本標準已改版，請參考新版本標準。(ASTM F647-94/(R)2006) |
| 788. | 17 Neurology 神經學 | TFDA-00608 | ASTM | ASTM F1542-94 (R2000) | 1994-10-01 | Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips | 本標準已廢除，無取代標準。 |
| 789. | 17 Neurology 神經學 | TFDA-00618 | IEC | IEC 60601-2-23:1999 | 1999-12-10 | Medical electrical equipment-Part 2-23:Particular requirements for the safety, including essential performance,of transcutaneous partial pressure monitoring equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-23:2011) |
| 790. | 17 Neurology 神經學 | TFDA-00628 | ISO | ISO 7197:1997 | 1997-11-01 | Neurosurgical implants — Sterile, single use hydrocephalus shunts and components | 本標準已改版，請參考新版本標準。(ISO 7197:2006/Cor 1:2007) |
| 791. | 17 Neurology 神經學 | TFDA-00630 | AAMI | AAMI NS28:1988/(R)2001 | 2001-07-23 | Intracranial pressure monitoring devices | 本標準已改版，請參考新版本標準。(AAMI NS28:1988/(R)2010) |
| 792. | 17 Neurology 神經學 | TFDA-00933 | AAMI | NS28:1988/(R)2006 | 2009-7-26 | Intracranial pressure monitoring devices | 本標準已改版，請參考新版本標準。(AAMI NS28:1988/(R)2010) |

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| 793. | 17 Neurology 神經學 | TFDA-01322 | AAMI | ANSI/AAMI NS4:1985(R2009) | 1985 (R2009) | Transcutaneous electrical nerve stimulators | 本標準已改版，請參考新版本標準。(AAMI NS4:2013) |
| 794. | 17 Neurology 神經學 | TFDA-01323 | IEC | IEC 60601-2-10:2012 ed2.0 | 2012-6-27 | Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators | 本標準已改版，請參考新版本標準。(IEC 60601-2-10:2016) |
| 795. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00001 | IEC | IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995 | 1988, Amendment 1: 1991-11, Amendment 2: 1995-03 | Medical Electrical Equipment - Part 1: General Requirements for Safety, Amendment 1 and Amendment 2 | 本標準已改版，請參考新版本標準。(IEC 60601-1:2005/Cor 1:2012) |
| 796. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00002 | IEC | IEC 60601-1-1：2000 | 2000-12 | Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems. | 本標準已廢除，請參考新標準。(IEC 60601-1:2005/Cor 1:2012) |
| 797. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00003 | IEC | IEC 60601-1-2：2001 | 2001-09 | Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests | 本標準已改版，請參考新版本標準。(IEC 60601-1-2:2014 ed4.0) |
| 798. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00004 | IEC | IEC 60601-1-3：1994 | 1994-07 | Medical Electrical Equipment - Part 1: General Requirements for Safety; General Requirements for Radiation Protection in Diagnostic X-Ray | 本標準已改版，請參考新版本標準。(IEC 60601-1-3:2013) |

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| 799. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00005 | IEC | IEC 60601-1-4：2000 | 2000-04 | Medical Electrical Equipment - Part 1: General requirements for safety; 4. Collateral Standard: Programmable electrical medical systems. | 本標準已廢除，請參考新標準。(IEC 60601-1:2005/Cor 1:2012) |
| 800. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00086 | IEC | IEC 60601-1-8:2003 | 2003-08 | Medical Electrical Equipment - Part 1-8: General Requirements for Safety - Collateral Standard: Alarm Systems - Requirements, Tests and Guidelines - General Requirements and Guidelines for Alarm Systems in Medical Equipment | 本標準已改版，請參考新版本標準。(IEC 60601-1-8:2012) |
| 801. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00433 | IEC | IEC 60601-1-8:2003/Amd 1:2006 | 2006-03-08 | Medical electrical equipment -- Part 1-8: General requirements for safety -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems | 本標準已改版，請參考新版本標準。(IEC 60601-1-8:2012) |
| 802. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00434 | IEC | IEC 60601-1:2005 | 2005-12-15 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | 本標準已改版，請參考新版本標準。(IEC 60601-1:2005/Cor 1:2012) |

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| 803. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00435 | IEC | IEC 60601-1-2: 2005 Consol. Ed. 2.1 (incl. am1) | 2004-11 | Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests | 本標準已改版，請參考新版本標準。(IEC 60601-1-2:2014 ed4.0) |
| 804. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00579 | IEC | IEC 60601-1-2 ed3.0 | 2007-03-20 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests | 本標準已改版，請參考新版本標準。(IEC 60601-1-2:2014 ed4.0) |
| 805. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00580 | IEC | IEC 60601-1-6:2006 | 2006-12-08 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | 本標準已改版，請參考新版本標準。(IEC 60601-1-6:2013 ed3.1 Consol. with am1 ) |
| 806. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00581 | IEC | CEI/IEC 60601-2-22:1995 | 1995-11-01 | Medical electrical equipment - Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment | 本標準已改版，請參考新版本標準。(IEC 60601-2-22:2012) |
| 807. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00583 | IEC | IEC 61326-1:2005 | 2005-12-15 | Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements | 本標準已改版，請參考新版本標準。(IEC 61326-1:2012) |

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| 808. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00585 | IEC | IEC/TR 62354:2005 | 2005-12-15 | General testing procedures for medical electrical equipment | 本標準已改版，請參考新版本標準。(IEC/TR 62354:2014) |
| 809. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00696 | IEC | IEC 60601-1-8 Edition 2.0 (2006-10) | 2006-10-25 | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems | 本標準已改版，請參考新版本標準。(IEC 60601-1-8:2012) |
| 810. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00889 | IEC | IEC 60601-1-6 ed3.0 : 2010 | 2010-1-27 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | 本標準已改版，請參考新版本標準。(IEC 60601-1-6:2013 ed3.1 Consol. with am1 ) |
| 811. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-00890 | IEC | IEC/TR 62354:2009 ed2.0 | 2009-10-14 | General testing procedures for medical electrical equipment | 本標準已改版，請參考新版本標準。(IEC/TR 62354:2014) |
| 812. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01006 | IEC | IEC 60601-1-11:2010 | 2010-4-28 | Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and | 本標準已改版，請參考新版本標準。(IEC 60601-1-11:2015) |

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| 813. | 19 General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01016 | ISO | ISO/TS 19218-1:2011 | 2011-5-15 | Medical devices — Hierarchical coding structure for adverse events — Part 1: Event-type codes - First Edition | 本標準已改版，請參考新版本標準。(ISO/TS 19218-1:2011 + A1:2013) |