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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主旨：公告「113年度醫療器材標準採認清單」及「歷年廢除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協和，並協助業者於醫療器材研發製造時能有所依循及參考，本署持續推動醫療器材採認工作，自民國93年至112年已陸續公告採認1,155項國內外醫療器材標準，並建置「醫療器材採認標準資料庫」，提供各界查詢。

二、本次公告「113年度醫療器材標準採認清單」，總計採認1,298項醫療器材標準，包含新增143項及原有採認標準1,155項(其中4項標準有更新改版)。

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者，另整理「歷年廢除之原採認醫療器材標準清單」，請儘早採用新版或相關替代標準。

四、本案另載於本署全球資訊網站(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、中華民國醫療器材商業同業公會全國聯合會、台北市醫療器材商業同業公會、新北市醫療器材商業同業公會、桃園市醫療器材商業同業公會、台中市醫療器材商業同業公會、彰化縣醫療器材商業同業公會、南投縣醫療器材商業同業公會、嘉義市醫療器材商業同業公會、台南市直轄市醫療器材商業同業公會、台南市醫療器材商業同業公會、高雄市醫療器材商業同業公會、台灣省醫療器材商業同業公會聯合會、屏東縣醫療器材商業同業公會、高雄市直轄市醫療器材商業同業公會、台灣口腔生物科技暨醫療器材產業發展促進協會、台灣牙科器材同業交流與公益協會、台北市生物技術服務商業同業

公會、社團法人中華民國助聽器同業聯合協進會、中華民國助聽器商業同業公會全國聯合會、台灣省助聽器商業同業公會聯合會、新北市助聽器商業同業公會、台南市助聽器商業同業公會、台北市助聽器商業同業公會、桃園市助聽器商業同業公會、台中市助聽器商業同業公會、彰化縣助聽器商業同業公會、高雄市助聽器商業同業公會、中華民國眼鏡發展協會、台灣區眼鏡工業同業公會、台北市眼鏡商業同業公會、台灣省鐘錶眼鏡商業同業公會聯合會、臺中市鐘錶眼鏡商業同業公會、高雄市鐘錶眼鏡商業同業公會、台灣生技醫療照護輔具協會、社團法人臺灣輔具產業發展協會、中華民國儀器商業同業公會全國聯合會、台北市儀器商業同業公會、桃園市儀器商業同業公會、台中市儀器商業同業公會、臺南市儀器商業同業公會、高雄市儀器商業同業公會、新竹市儀器商業同業公會、台灣橡膠暨彈性體工業同業公會、台灣省橡膠製品商業同業公會聯合會、台灣醫療器材門市發展協會、台灣生物產業發展協會、中華民國全國商業總會、中華民國全國工業總會、台灣先進醫療科技發展協會、台灣自我照護產業協會、臺灣美國商會、歐洲在臺商務協會、台北市日本工商會、台灣研發型生技新藥發展協會、台灣醫藥品法規學會、經濟部工業局、南港軟體工業園區二期管理委員會、國家科學及技術委員會新竹科學園區管理局、台灣科學園區科學工業同業公會、國家科學及技術委員會南部科學園區管理局、國家科學及技術委員會中部科學園區管理局、財團法人金屬工業研究發展中心(高雄)、財團法人塑膠工業技術發展中心、財團法人台灣商品檢測驗證中心、財團法人醫藥品查驗中心、財團法人醫藥工業技術發展中心、財團法人工業技術研究院量測技術發展中心、社團法人中華無菌製劑協會、財團法人生物技術開發中心、台灣省進出口商業同業公會聯合會、台北市進出口商業同業公會、新北市進出口商業同業公會、桃園市進出口商業同業公會、台中市進出口商業同業公會、台中縣進出口商業同業公會、台南市進出口商業同業公會、台南縣進出口商業同業公會、高雄縣進出口商業同業公會、高雄市進出口商業同業公會、台灣區電機電子工業同業公會、台灣臨床檢驗標準協會、台灣藥物臨床研究協會、台北市西藥商業同業公會、台灣製藥工業同業公會、中華民國西藥代理商業同業公會、中華民國西藥商業同業公會全國聯合會、台灣省西藥商業同業公會聯合會、中華民國開發性製藥研究協會、中華民國製藥發展協會、台北市西藥代理商業同業公會、台灣藥品行銷暨管理協會、中華生物醫學工程協進會、中華民國金屬家具商業同業公會全國聯合會、中華民國生物醫學工程學會、台灣顯示器產業聯合總會、新北市生技產業發展聯盟、台灣健康資訊產業整合協會、台北市電腦商業同業公會、中華民國資訊軟體協會、財團法人資訊工業策進會、台灣健康資訊交換標準第七層協定協會、台灣數位安全聯盟、財團法人中華民國國家資訊基本建設產業發展協進會、社團法人台灣生技產業聯盟、台灣隱形眼鏡產業發展協會

副本：

署長 莊聲宏

檔　　號：
保存年限：

衛生福利部食品藥物管理署　公告

發文日期：中華民國113年8月23日
發文字號：FDA器字第1131606912號
附件：如文

主旨：公告「113年度醫療器材標準採認清單」及「歷年廢除之原採認醫療器材標準清單」。

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協和，並協助業者於醫療器材研發製造時能有所依循及參考，本署持續推動醫療器材採認工作，自民國93年至112年已歷經12次公告，目前共採認1,155項國內外醫療器材標準，以提供業者作為研發製造醫療器材之參考。

二、本次公告「113年度醫療器材標準採認清單」(附件1)，共採認1,298項醫療器材標準，包含新增143項及原有採認標準1,155項(其中4項標準有更新改版)。

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者，另整理「歷年廢除之原採認醫療器材標準清單」(附件2)共255項，請儘早採用新版或相關替代標準。

四、本案另載於本署全球資訊網站(www.fda.gov.tw)之公告區及醫療器材法規專區。訊網站(www.fda.gov.tw)之公告區及醫療器材法規專區。

署長 莊聲宏

附件 1、113 年度醫療器材標準採認清單(共 1,298 項)

編號	標準類別	標準組織名稱	標準號碼	版本/年份	標準名稱	備註說明
1	1 Anesthesias 麻醉學	ISO	ISO 13320	2020	Particle size analysis — Laser diffraction methods	原採認標準
2	1 Anesthesias 麻醉學	ISO	ISO 80601-2-84	2020	Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment	原採認標準
3	1 Anesthesias 麻醉學	ISO	ISO 10651-4	2002	Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators	原採認標準
4	1 Anesthesias 麻醉學	ISO	ISO 10651-5	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
5	1 Anesthesias 麻醉學	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
6	1 Anesthesias 麻醉學	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
7	1 Anesthesias 麻醉學	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
8	1 Anesthesias 麻醉學	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
9	1 Anesthesias 麻醉	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

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10	1 Anesthesias 麻醉學	ISO	ISO 5362	2006	Anaesthetic reservoir bags	原採認標準
11	1 Anesthesias 麻醉學	CNS	CNS 14776	2022	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
12	1 Anesthesias 麻醉學	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
13	1 Anesthesias 麻醉學	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
14	1 Anesthesias 麻醉學	ISO	ISO 23328-1	2003	Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance	原採認標準
15	1 Anesthesias 麻醉學	ISO	ISO 23328-2	2002	Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects	原採認標準
16	1 Anesthesias 麻醉學	ISO	ISO 26782	2009	Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans	原採認標準
17	1 Anesthesias 麻醉學	ASTM	ASTM G175	2021	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
18	1 Anesthesias 麻醉學	ISO	ISO 10079-2	2022	Medical suction equipment - Part 2: Manually powered suction equipment	原採認標準
19	1 Anesthesias 麻醉	ISO	ISO 10079-3	2022	Medical suction equipment Part 3: Suction equipment powered	原採認標準

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20	1 Anesthesias 麻醉學	ISO	ISO 14408	2016	Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information	原採認標準
21	1 Anesthesias 麻醉學	ISO	ISO 23747	2015	Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans	原採認標準
22	1 Anesthesias 麻醉學	ISO	ISO 5360	2016	Anaesthetic vaporizers - Agent-specific filling systems	原採認標準
23	1 Anesthesias 麻醉學	ISO	ISO 5361	2016	Anaesthetic and respiratory equipment — Tracheal tubes and connectors	原採認標準
24	1 Anesthesias 麻醉學	ISO	ISO 5364	2016	Anaesthetic and respiratory equipment - Oropharyngeal airways	原採認標準
25	1 Anesthesias 麻醉學	ISO	ISO 5366	2016	Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors	原採認標準
26	1 Anesthesias 麻醉學	ISO	ISO 5367	2014	Breathing Tubes intended for use with Anaesthetic Apparatus and Ventilators	原採認標準
27	1 Anesthesias 麻醉學	ISO	ISO 7376	2020	Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation	原採認標準
28	1 Anesthesias 麻醉學	ISO	ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	原採認標準
29	1 Anesthesias 麻醉學	ISO	ISO 80601-2-67	2020	Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	原採認標準

30	1 Anesthesias 麻醉學	ISO	ISO 80601-2-69	2020	Medical electrical equipment — Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment	原採認標準
31	1 Anesthesias 麻醉學	ISO	ISO 10524-1	2018	Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow-metering devices	原採認標準
32	1 Anesthesias 麻醉學	ISO	ISO 10524-2	2018	Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators	原採認標準
33	1 Anesthesias 麻醉學	ISO	ISO 17510	2015	Medical devices - Sleep apnoea breathing therapy - Masks and application accessories	原採認標準
34	1 Anesthesias 麻醉學	ISO	ISO 5356-1	2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets	原採認標準
35	1 Anesthesias 麻醉學	ISO	ISO 5359	2017	Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases	原採認標準
36	1 Anesthesias 麻醉學	ISO	ISO 80601-2-55	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
37	1 Anesthesias 麻醉學	ISO	ISO 80601-2-70	2020	Medical electrical equipment — Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment	原採認標準
38	1 Anesthesias 麻醉學	ISO	ISO 80601-2-74	2021	Medical electrical equipment—Part 2–74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	原採認標準
39	1 Anesthesias 麻醉學	ISO	ISO 10079-1	2022	Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements	原採認標準

40	1 Anesthesias 麻醉學	ISO	ISO 80601-2-13	2022	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	原採認標準
41	1 Anesthesias 麻醉學	EN	EN ISO 27427	2019	Anaesthetic and respiratory equipment - Nebulizing systems and components	原採認標準
42	1 Anesthesias 麻醉學	ISO	ISO 10524-3	2019	Pressure regulators for use with medical gases – Part 3:Pressure regulators integrated with cylinder valves	原採認標準
43	1 Anesthesias 麻醉學	ISO	ISO 80369-1	2018	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements	原採認標準
44	1 Anesthesias 麻醉學	ISO	ISO 80601-2-12	2020	Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	原採認標準
45	1 Anesthesias 麻醉學	ISO	ISO 8836	2019	Suction catheters for use in the respiratory tract	原採認標準
46	1 Anesthesias 麻醉學	ISO	ISO 5356-2	2019	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	原採認標準
47	1 Anesthesias 麻醉學	ISO	ISO 26825	2020	Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours design and performance	原採認標準
48	1 Anesthesias 麻醉學	ISO	ISO 80601-2-87	2021	Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators	原採認標準
49	1 Anesthesias 麻醉學	NFPA	99:2021	2021	Health Care Facilities Code	113 年度新增採認標準

50	1 Anesthesias 麻醉學	ISO	16628 Second edition 2022-06	2022	Anaesthetic and respiratory equipment - Tracheobronchial tubes	113 年度新增採認標準
51	1 Anesthesias 麻醉學	ISO	10079-2 Fourth edition 2022-03	2022	Medical suction equipment - Part 2: Manually powered suction equipment	113 年度新增採認標準
52	1 Anesthesias 麻醉學	ISO	10079-3 Fourth edition 2022-03	2022	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source	113 年度新增採認標準
53	1 Anesthesias 麻醉學	ISO	10079-4 First edition 2021-08	2021	Medical suction equipment - Part 4: General requirements	113 年度新增採認標準
54	1 Anesthesias 麻醉學	ISO	10079-1 Fourth edition 2022-03	2022	Medical suction equipment - Part 1: Electrically powered suction equipment	113 年度新增採認標準
55	1 Anesthesias 麻醉學	ASME	PVHO-1-2019	2019	Safety Standard for Pressure Vessels for Human Occupancy	113 年度新增採認標準
56	1 Anesthesias 麻醉學	ISO	18778 Second edition 2022-06	2022	Respiratory equipment - Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors	113 年度新增採認標準
57	1 Anesthesias 麻醉學	ISO	80601-2-84 First edition 2020-07	2020	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment	113 年度新增採認標準
58	2 Biocompatibility 生物相容性	ISO	ISO 10993-14	2001	Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics	原採認標準
59	2 Biocompatibility 生物相容性	ISO	ISO 10993-17	2002	Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances	原採認標準
60	2 Biocompatibility 生物相容性	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	原採認標準

					sterilisation residuals	
61	2 Biocompatibility 生物相容性	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
62	2 Biocompatibility 生物相容性	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
63	2 Biocompatibility 生物相容性	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
64	2 Biocompatibility 生物相容性	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
65	2 Biocompatibility 生物相容性	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
66	2 Biocompatibility 生物相容性	ISO	ISO/TS 10993-20	2006	Biological evaluation of medical devices —Part 20: Principles and methods for immunotoxicology testing of medical devices	原採認標準
67	2 Biocompatibility 生物相容性	ISO	ISO 10993-2	2006	Biological evaluation of medical devices -- Part 2: Animal welfare requirements	原採認標準
68	2 Biocompatibility 生物相容性	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
69	2 Biocompatibility	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

	生物相容性					
70	2 Biocompatibility 生物相容性	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
71	2 Biocompatibility 生物相容性	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
72	2 Biocompatibility 生物相容性	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
73	2 Biocompatibility 生物相容性	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
74	2 Biocompatibility 生物相容性	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
75	2 Biocompatibility 生物相容性	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
76	2 Biocompatibility 生物相容性	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
77	2 Biocompatibility 生物相容性	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
78	2 Biocompatibility 生物相容性	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
79	2 Biocompatibility 生物相容性	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
80	2 Biocompatibility 生物相容性	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
81	2 Biocompatibility	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	原採認標準

	生物相容性				原理與方法	
82	2 Biocompatibility 生物相容性	ISO	ISO 10993-5	2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	原採認標準
83	2 Biocompatibility 生物相容性	ISO	ISO 10993-13	2010	Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices	原採認標準
84	2 Biocompatibility 生物相容性	ISO	ISO 10993-10	2021	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	原採認標準
85	2 Biocompatibility 生物相容性	ASTM	ASTM F750	2020	Standard Practice for Evaluating Acute Systemic Toxicity of Material Extracts by Systemic Injection in the Mouse	原採認標準
86	2 Biocompatibility 生物相容性	ASTM	ASTM F813	2020	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	原採認標準
87	2 Biocompatibility 生物相容性	ISO	ISO 10993-12	2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	原採認標準
88	2 Biocompatibility 生物相容性	ISO	ISO 10993-3	2014	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	原採認標準
89	2 Biocompatibility 生物相容性	ISO	ISO 10993-6	2016	Biological evaluation of medical devices, Part 6: Tests for local effects after implantation	原採認標準
90	2 Biocompatibility 生物相容性	ISO	AAMI/ISO TIR37137	2014	Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants	原採認標準
91	2 Biocompatibility 生物相容性	ISO	ISO/TR 10993-33	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
92	2 Biocompatibility	ASTM	ASTM F720	2017	Standard Practice for Testing Guinea Pigs for Contact Allergens:	原採認標準

	生物相容性				Guinea Pig Maximization Test	
93	2 Biocompatibility 生物相容性	ISO	ISO 10993-11	2017	Biological evaluation of medical devices -- Part 11:Tests for systemic toxicity	原採認標準
94	2 Biocompatibility 生物相容性	ISO	ISO 10993-16	2017	Biological evaluation of medical devices -- Part 16:Toxicokinetic study design for degradation products and leachables	原採認標準
95	2 Biocompatibility 生物相容性	ISO	ISO 10993-4	2017	Biological evaluation of medical devices -- Part 4:Selection of tests for interactions with blood	原採認標準
96	2 Biocompatibility 生物相容性	ISO	ISO 18562-1	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
97	2 Biocompatibility 生物相容性	ISO	ISO 18562-2	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter	原採認標準
98	2 Biocompatibility 生物相容性	ISO	ISO 18562-3	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
99	2 Biocompatibility 生物相容性	ISO	ISO 18562-4	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate	原採認標準
100	2 Biocompatibility 生物相容性	ASTM	ASTM F2382	2018	Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)	原採認標準
101	2 Biocompatibility 生物相容性	ISO	ISO 10993-1	2018	Biological evaluation of medical devices -- Part 1:Evaluation and testing within a risk management process	原採認標準
102	2 Biocompatibility	ASTM	ASTM F2148	2018	Standard Practice for Evaluation of Delayed Contact	原採認標準

	生物相容性				Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	
103	2 Biocompatibility 生物相容性	ISO	ISO 10993-15	2019	Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals an	原採認標準
104	2 Biocompatibility 生物相容性	ISO	ISO 10993-18	2022	Biological evaluation of medical devices —Part 18: Chemical characterization of materials	原採認標準
105	2 Biocompatibility 生物相容性	ISO	ISO/TS 10993-19	2020	Biological evaluation of medical devices —Part 19: Physico-chemical, morphological and topographical characterization of materials	原採認標準
106	2 Biocompatibility 生物相容性	ISO	ISO 10993-9	2019	Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products	原採認標準
107	2 Biocompatibility 生物相容性	ASTM	ASTM F719	2020	Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	原採認標準
108	2 Biocompatibility 生物相容性	ASTM	ASTM F749	2020	Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	原採認標準
109	2 Biocompatibility 生物相容性	ISO	ISO 10993-7	2019	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals	原採認標準
110	2 Biocompatibility 生物相容性	ASTM	ASTM F619	2020	Standard Practice for Extraction of Materials Used in Medical Devices	原採認標準
111	2 Biocompatibility 生物相容性	ASTM	ASTM F1408	2020	Standard Practice for Subcutaneous Screening Test for Implant Materials	原採認標準
112	2 Biocompatibility	CEN	EN ISO	2021	Biological evaluation of medical devices - Part 23: Tests for	原採認標準

	生物相容性	ISO	10993-23		irritation	
113	2 Biocompatibility 生物相容性	CEN	EN ISO 10993-10:2023	2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)	113 年度新增採認標準
114	2 Biocompatibility 生物相容性	ASTM	F1983-23	2023	Standard Practice for Assessment of Selected Tissue Effects of Absorbable Biomaterials for Implant Applications	113 年度新增採認標準
115	2 Biocompatibility 生物相容性	ISO	10993-2 Third edition 2022-11	2022	Biological Evaluation of medical devices - Part 2: Animal welfare requirements	113 年度新增採認標準
116	2 Biocompatibility 生物相容性	ISO	10993-12 Fifth edition 2021-01	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	113 年度新增採認標準
117	2 Biocompatibility 生物相容性	ASTM	F1904-23	2023	Standard Guide for Testing the Biological Responses to Medical Device Particulate Debris and Degradation Products in vivo	113 年度新增採認標準
118	2 Biocompatibility 生物相容性	ASTM	F763-22	2022	Standard Practice for Short-Term Intramuscular Screening of Implantable Medical Device Materials	113 年度新增採認標準
119	2 Biocompatibility 生物相容性	ISO	10993-18 Second edition 2020-01 Amendment 1 2022-05	2022	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process [Including Amendment 1 (2022)].	113 年度新增採認標準
120	2 Biocompatibility 生物相容性	ISO	10993-10 Fourth edition 2021-11	2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	113 年度新增採認標準
121	3 Cardiovascular 心臟血管醫學	ISO	ISO 11318	2002	Cardiac Defibrillators - Connector Assembly for Implantable Defibrillators - Dimensional and Test Requirements	原採認標準
122	3 Cardiovascular 心臟血管醫學	CNS	CNS 13075	2007	非侵入式自動血壓計	原採認標準

123	3 Cardiovascular 心臟血管醫學	CNS	CNS 15041-1	2018	非侵入式血壓計－第 1 部：一般規定	原採認標準
124	3 Cardiovascular 心臟血管醫學	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
125	3 Cardiovascular 心臟血管醫學	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
126	3 Cardiovascular 心臟血管醫學	OIML	OIML R16-2	2005	Non-invasive automated sphygmomanometers	原採認標準
127	3 Cardiovascular 心臟血管醫學	CEN	EN 1060-4	2004	Non-invasive sphygmomanometers—Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	原採認標準
128	3 Cardiovascular 心臟血管醫學	AAMI	AAMI EC53	2020	ECG trunk cables and patient leadwires	原採認標準
129	3 Cardiovascular 心臟血管醫學	AAMI	ANSI/AAMI EC57	2020	Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms	原採認標準
130	3 Cardiovascular 心臟血管醫學	AAMI	AAMI/IEC 60601-2-4	2018	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	原採認標準
131	3 Cardiovascular 心臟血管醫學	CEN	EN ISO 81060-1	2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type - CORR: July 31, 2012	原採認標準
132	3 Cardiovascular 心臟血管醫學	ISO	ISO 5841-2	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

133	3 Cardiovascular 心臟血管醫學	IEC	IEC 60601-2-34	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
134	3 Cardiovascular 心臟血管醫學	IEC	IEC 60601-2-47	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
135	3 Cardiovascular 心臟血管醫學	ISO	ISO 10555-4	2013	Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters - Second Edition	原採認標準
136	3 Cardiovascular 心臟血管醫學	ISO	ISO 17475	2006	Corrosion of metals and alloys -- Electrochemical test methods -- Guidelines for conducting potentiostatic and potentiodynamic polarization measurements	原採認標準
137	3 Cardiovascular 心臟血管醫學	ISO	ISO 2248	1985	Packaging -- Complete, filled transport packages -- Vertical impact test by dropping	原採認標準
138	3 Cardiovascular 心臟血管醫學	ISO	ISO 25539-2	2020	Cardiovascular implants — Endovascular devices — Part 2: Vascular stents	原採認標準
139	3 Cardiovascular 心臟血管醫學	ISO	ISO 25539-3	2011	Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters	原採認標準
140	3 Cardiovascular 心臟血管醫學	ISO	ISO 5841-3	2013	Implants for surgery -- Cardiac pacemakers -- Part 3: Low-profile connectors (IS-1) for implantable pacemakers	原採認標準
141	3 Cardiovascular 心臟血管醫學	ISO	ISO 81060-1	2007	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type.	原採認標準
142	3 Cardiovascular 心臟血管醫學	ISO	ISO 8318	2000	Packaging - Complete, Filled Transport Packages and Unit Laods - Sinusoidal Vibration Tests Using a Variable Frequency - Second Edition	原採認標準

143	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2082/F2082M	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
144	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F3036	2021	Standard Guide for Testing Absorbable Stents	原採認標準
145	3 Cardiovascular 心臟血管醫學	IEC	IEC 60601-2-27	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
146	3 Cardiovascular 心臟血管醫學	ISO	ISO 15676	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
147	3 Cardiovascular 心臟血管醫學	ISO	ISO 25539-1	2017	Cardiovascular implants— Endovascular devices—Part 1: Endovascular prostheses	原採認標準
148	3 Cardiovascular 心臟血管醫學	ISO	ISO 5840-1	2021	Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements	原採認標準
149	3 Cardiovascular 心臟血管醫學	ISO	ISO 5840-2	2021	Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes	原採認標準
150	3 Cardiovascular 心臟血管醫學	ISO	ISO 5840-3	2021	Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques	原採認標準
151	3 Cardiovascular 心臟血管醫學	ISO	ISO 7198	2016	Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches	原採認標準
152	3 Cardiovascular 心臟血管醫學	ISO	ISO 12417-1	2015	Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements	原採認標準

153	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2004	2017	Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis	原採認標準
154	3 Cardiovascular 心臟血管醫學	IEC	IEC 60601-2-4	2018	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	原採認標準
155	3 Cardiovascular 心臟血管醫學	IEC	IEC 80601-2-30	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
156	3 Cardiovascular 心臟血管醫學	IEC	IEC 80601-2-49	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
157	3 Cardiovascular 心臟血管醫學	ISO	ISO 11070	2018	Sterile single-use intravascular introducers, dilators and guidewires	原採認標準
158	3 Cardiovascular 心臟血管醫學	ISO	ISO 80601-2-61	2017	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	原採認標準
159	3 Cardiovascular 心臟血管醫學	AAMI	ANSI/AAMI EC12	2020	Disposable ECG electrodes	原採認標準
160	3 Cardiovascular 心臟血管醫學	AAMI	IEC 60601-2-25	2016	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.	原採認標準
161	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2081	2022	Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents	原採認標準
162	3 Cardiovascular	ASTM	ASTM F1984	2018	Standard Practice for Testing for Whole Complement Activation	原採認標準

	心臟血管醫學				in Serum by Solid Materials	
163	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2079	2017	Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon Expandable Stents	原採認標準
164	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2394	2017	Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System	原採認標準
165	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F746	2021	Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	原採認標準
166	3 Cardiovascular 心臟血管醫學	ISO	ISO 8637-3	2018	Extracorporeal systems for blood purification - Part 3: Plasmafilters	原採認標準
167	3 Cardiovascular 心臟血管醫學	ISO	ISO 81060-2	2020	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type - Second Edition	原採認標準
168	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F3320	2018	Standard Guide for Coating Characterization of Drug Coated Balloons	原採認標準
169	3 Cardiovascular 心臟血管醫學	ISO	ISO 5910	2018	Cardiovascular implants and extracorporeal systems - Cardiac valve repair devices	原採認標準
170	3 Cardiovascular 心臟血管醫學	AAMI	AAMI/ISO 14117	2019	Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices.	原採認標準
171	3 Cardiovascular 心臟血管醫學	ASTM	ASTM G71	2019	Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes	原採認標準
172	3 Cardiovascular 心臟血管醫學	IEC	IEC 60601-2-31	2020	Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	原採認標準

173	3 Cardiovascular 心臟血管醫學	ISO	ISO 14708-2	2019	Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers	原採認標準
174	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F138	2020	Standard Specification for Wrought 18 Chromium 14 Nickel 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	原採認標準
175	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2942	2021	Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents	原採認標準
176	3 Cardiovascular 心臟血管醫學	ISO	ISO 15674	2020	Cardiovascular implants and artificial organs - Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	原採認標準
177	3 Cardiovascular 心臟血管醫學	ISO	ISO 15675	2020	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	原採認標準
178	3 Cardiovascular 心臟血管醫學	ISO	ISO 7199	2020	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)	原採認標準
179	3 Cardiovascular 心臟血管醫學	ISO	ISO/TS 17137	2022	Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants	原採認標準
180	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F1830	2019	Standard Practice for Collection and Preparation of Blood for Dynamic In Vitro Evaluation of Hemolysis in Blood Pumps	原採認標準
181	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F1841	2021	Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps	原採認標準
182	3 Cardiovascular 心臟血管醫學	IEEE	IEEE Std 1708	2019	Standard for Wearable, Cuffless Blood Pressure Measuring Devices [including: Amendment 1 (2019)]	原採認標準
183	3 Cardiovascular 心臟血管醫學	ISO	ISO/TS 81060-5	2020	Non-invasive sphygmomanometers - Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for	原採認標準

					testing of automated non-invasive sphygmomanometers	
184	3 Cardiovascular 心臟血管醫學	ISO	ISO 14708-5	2020	Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices	原採認標準
185	3 Cardiovascular 心臟血管醫學	AAMI	AAMI TIR42	2021	Evaluation of Particulates Associated with Vascular Medical Devices	原採認標準
186	3 Cardiovascular 心臟血管醫學	ISO	ISO 18193	2021	Cardiovascular implants and artificial organs - Cannulae for extracorporeal circulation	原採認標準
187	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F3172	2021	Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices	原採認標準
188	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F3067	2021	Standard Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents	原採認標準
189	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2606	2021	Standard Guide for Three-Point Bending of Balloon-Expandable Vascular Stents and Stent Systems	原採認標準
190	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2514	2021	Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading	原採認標準
191	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F3505	2021	Standard Test Method for Stent and Endovascular Prosthesis Kink Resistance	原採認標準
192	3 Cardiovascular 心臟血管醫學	ISO	14708-2 Third edition 2019-09	2019	Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers	113 年度新增採認標準
193	3 Cardiovascular 心臟血管醫學	ISO	81060-3 First edition 2022-12	2022	Non-invasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type	113 年度新增採認標準
194	3 Cardiovascular 心臟血管醫學	ISO	14708-6 Second edition 2019-09	2019	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable	113 年度新增採認標準

					defibrillators)	
195	3 Cardiovascular 心臟血管醫學	ISO	11658 First edition 2012-05-15	2012	Cardiovascular implants and extracorporeal systems - Blood/tissue contact surface modifications for extracorporeal perfusion systems	113 年度新增採認標準
196	3 Cardiovascular 心臟血管醫學	ASTM	F2477-23	2023	Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents and Endovascular Prostheses	113 年度新增採認標準
197	3 Cardiovascular 心臟血管醫學	ANSI AAMI	PC76:2021	2021	Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging	113 年度新增採認標準
198	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI	ADA Specification No.27	1993	Resin-Based Filling Materials	原採認標準
199	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6360-3	2005	Dentistry -- Number coding system for rotary instruments -- Part 3: Specific characteristics of burs and cutters	原採認標準
200	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6360-4	2004	Dentistry -- Number coding system for rotary instruments -- Part 4: Specific characteristics of diamond instruments	原採認標準
201	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6360-6	2004	Dentistry -- Number coding system for rotary instruments -- Part 6: Specific characteristics of abrasive instruments	原採認標準
202	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6360-7	2006	Dentistry – Number coding system for rotary instruments – Part 7: Specific characteristics of mandrels and special instruments	原採認標準
203	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13397-1	1995	Periodontal curettes, dental scalers and excavators -- Part 1: General requirements	原採認標準
204	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13397-3	1996	Periodontal curettes, dental scalers and excavators -- Part 3: Dental scalers -- H-type	原採認標準

205	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13397-4	1997	Periodontal curettes, dental scalers and excavators -- Part 4: Dental excavators -- Discoid-type	原採認標準
206	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 15854	2021	Dentistry – Casting and baseplate waxes	原採認標準
207	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6877	2021	Dentistry -- Root-canal obturating points	原採認標準
208	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9917-1	2007	Dentistry -- Water-based cements -- Part 1: Powder/liquid acid-base cements	原採認標準
209	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9168	2009	Dentistry -- Hose connectors for air driven dental handpieces	原採認標準
210	4 Dental/ENT 牙科學/耳鼻喉科學	CEN	EN 1639	2009	Dentistry. Medical devices for dentistry. Instruments	原採認標準
211	4 Dental/ENT 牙科學/耳鼻喉科學	CEN	EN 1640	2009	Dentistry. Medical devices for dentistry. Equipment	原採認標準
212	4 Dental/ENT 牙科學/耳鼻喉科學	CEN	EN 1641	2009	Dentistry. Medical devices for dentistry. Materials	原採認標準
213	4 Dental/ENT 牙科學/耳鼻喉科學	CEN	EN 1642	2011	Dentistry. Medical devices for dentistry. Dental implants	原採認標準
214	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13397-2	2012	Dentistry – Periodontal curettes, dental scalers and excavators – Part 2:Periodontal curettes of Gr-type	原採認標準
215	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 21563	2013	Dentistry - Hydrocolloid impression materials - First Edition	原採認標準
216	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 3107	2011	Dentistry — Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements - Fourth Edition	原採認標準

217	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6360-2	2011	Dentistry — Number coding system for rotary instruments — Part 2: Shapes AMENDMENT 1 - Second Edition	原採認標準
218	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6876	2012	Dentistry - Root canal sealing materials - Third Edition	原採認標準
219	4 Dental/ENT 牙科學/耳鼻喉科學	ADA	ANSI/ADA 96	2012	ANSI/ADA Standard No. 96—Dental Water-based Cements: 2012	原採認標準
220	4 Dental/ENT 牙科學/耳鼻喉科學	AAMI	AAMI CI86	2017	Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting	原採認標準
221	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10139-2	2016	Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use	原採認標準
222	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 14801	2016	Dentistry - Implants - Dynamic loading test for endosseous dental implants	原採認標準
223	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 22674	2016	Dentistry -- Metallic materials for fixed and removable restorations and appliances	原採認標準版本更新
224	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6360-1	2007	Dentistry — Number coding system for rotary instruments — Part 1: General characteristics	原採認標準
225	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6874	2015	Dentistry — Polymer-based pit and fissure sealants	原採認標準
226	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7494-2	2015	Dentistry - Dental units - Part 2: Air, water, suction and wastewater systems - Second Edition	原採認標準
227	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10139-1	2018	Dentistry - Soft lining materials for removable dentures - Part 1:Materials for short-term use	原採認標準
228	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10477	2020	Dentistry -- Polymer-based crown and bridge materials	原採認標準

229	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 11137-3	2017	Sterilization of health care products —Radiation —Part 3:Guidance on dosimetric aspects	原採認標準
230	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 14457	2017	Dentistry -- Handpieces and motors	原採認標準
231	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 22112	2017	Dentistry - Artificial teeth for dental prostheses	原採認標準
232	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7491	2000	Dental materials—Determination of colour stability	原採認標準
233	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7494-1	2018	Dentistry -- Dental units -- Part 1: General requirements and test methods	原採認標準
234	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9917-2	2017	Dentistry - Water-based cements - Part 2: Resin-modified cements	原採認標準
235	4 Dental/ENT 牙科學/耳鼻喉科學	ASA	ASA S3.6	2018	American National Standard Specification for Audiometers	原採認標準
236	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6872	2018	Dentistry - Ceramic materials	原採認標準
237	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9693	2019	Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems	原採認標準
238	4 Dental/ENT 牙科學/耳鼻喉科學	ASTM	ASTM F1088	2018	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	原採認標準
239	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7405	2018	Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry	原採認標準
240	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 17730	2020	Dentistry - Fluoride varnishes	原採認標準

241	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 4049	2019	Dentistry -- Polymer-based restorative materials	原採認標準
242	4 Dental/ENT 牙科學/耳鼻喉科學	IEC	IEC 80601-2-60	2019	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	原採認標準
243	4 Dental/ENT 牙科學/耳鼻喉科學	ASA	ASA S3.22-2014	2020	Specification of Hearing Aid Characteristics	原採認標準
244	4 Dental/ENT 牙科學/耳鼻喉科學	IEC	IEC 60601-2-66	2019	Medical electrical equipment Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument system	原採認標準
245	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO/TR 22442-4	2010	Medical devices utilizing animal tissues and their derivatives — Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy22agents and validation assays for those processes	原採認標準
246	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10650	2018	Dentistry — Powered polymerization activators	原採認標準
247	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ASA	ANSI ASA S3.7	2020	American National Standard Method for Coupler Calibration of Earphones	原採認標準
248	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10271	2020	Dentistry - Corrosion test methods for metallic materials	原採認標準
249	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10873 Second	2021	Dentistry - Denture adhesives	原採認標準
250	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 37	2020	Dental Abrasive Powders	原採認標準

251	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 87	2014	Dental Impression Trays	原採認標準
252	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 43	2020	Electrically Powered Dental Amalgamators	原採認標準
253	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 18556	2016	Dentistry - Intraoral spatulas	原採認標準
254	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 136	2020	Products for External Tooth Bleaching	原採認標準
255	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ASA	ANSI ASA S3.22-2014 (Reaffirmed 2020)	2020	American National Standard Specification of Hearing Aid Characteristics	113 年度新增採認標準
256	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 4823:2021	2021	Elastomeric impression and bite registration materials	113 年度新增採認標準
257	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ADA	Standard No. 139-2020	2020	Dental Base Polymers	113 年度新增採認標準
258	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 21606:2022	2022	Dentistry - Elastomeric auxiliaries for use in orthodontics	113 年度新增採認標準
259	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 22052:2020	2020	Dentistry - Compressed air source equipment	113 年度新增採認標準
260	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13504:2012	2012	Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment	113 年度新增採認標準
261	4 Dental/ENT 牙	ISO	ISO	2019	Implants for surgery - Active implantable medical devices - Part	113 年度新增採

	科學/耳鼻喉科學		14708-7:2019		7: Particular requirements for cochlear and auditory brainstem implant systems	認標準
262	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10637:2018	2018	Dentistry - Central suction source equipment	113 年度新增採認標準
263	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 4049:2019	2019	Dentistry - Polymer-based restorative materials	113 年度新增採認標準
264	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 21563:2021	2021	Dentistry - Hydrocolloid impression materials	113 年度新增採認標準
265	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9873:2019	2019	Dentistry - Intra-oral mirrors	113 年度新增採認標準
266	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 20126:2022	2022	Dentistry - Manual toothbrushes - General requirements and test methods	113 年度新增採認標準
267	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 10477:2020	2020	Dentistry - Polymer-based crown and veneering materials	113 年度新增採認標準
268	4 Dental/ENT 牙科學/耳鼻喉科學	ANSI ADA	Standard No. 41-2020	2020	Evaluation of Biocompatibility of Medical Devices Used in Dentistry	113 年度新增採認標準
269	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 3107:2022	2022	Dentistry - Zinc oxide-eugenol cements and non-eugenol zinc oxide cements	113 年度新增採認標準
270	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 22674:2022	2022	Dentistry - Metallic materials for fixed and removable restorations and appliances	113 年度新增採認標準
271	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9333:2022	2022	Dentistry - Brazing materials	113 年度新增採認標準
272	5 General I (QS/RM) 通用(品質管理系統	ISO	ISO 10012	2003	Quality assurance requirements for measuring equipment Part 1: Metrological confirmation system for measuring equipment	原採認標準

	/風險管理)					
273	5 General I (QS/RM) 通用(品質管理系統/風險管理)	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
274	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS14989	2006	醫療器材風險管理	原採認標準
275	5 General I (QS/RM) 通用(品質管理系統/風險管理)	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
276	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 14155	2020	Clinical investigation of medical devices for human subjects -- Good clinical practice	原採認標準
277	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	AAMI TIR69	2020	Risk management of radio-frequency wireless coexistence for medical devices and systems	原採認標準
278	5 General I (QS/RM) 通用(品質管理系統/風險管理)	EN	EN 45502-1	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
279	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	IEC TR 80002-1	2009	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software	原採認標準
280	5 General I (QS/RM) 通用(品質管理系統	ISO	ISO 13485	2016	Medical devices — Quality management systems — Requirements for regulatory purposes	原採認標準

	/風險管理)					
281	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 15223-1	2021	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
282	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 16061	2021	Instruments for use in association with non-active surgical implants — General requirements	原採認標準
283	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 16142-1	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
284	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 16142-2	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
285	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 80369-6	2016	Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications	原採認標準
286	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	AAMI HE75	2018	Human factors engineering - Design of medical devices	原採認標準
287	5 General I (QS/RM)	ISO	IEC 80369-5	2021	Small-bore connectors for liquids and gases in healthcare	原採認標準

	通用(品質管理系統/風險管理)				applications—Part 5: Connectors for limb cuff inflation applications	
288	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 14971	2019	Medical devices -- Application of risk management to medical devices	原採認標準
289	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO/TR 24971	2020	Medical devices — Guidance on the application of ISO 14971	原採認標準
290	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	IEC 62366-1	2020	Medical devices –Part 1: Application of usability engineering to medical devices	原採認標準
291	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 80369-3	2019	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications	原採認標準
292	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 7010	2019	Graphical symbols - Safety colours and safety signs - Registered safety signs	原採認標準
293	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS 62366-1 T5073-1	2021	"醫療器材－第 1 部：醫療器材可用性工程之應用 Medical devices − Part 1: Application of usability engineering to medical devices	原採認標準
294	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	18250-3 First edition 2018-06	2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 3: Enteral application	113 年度新增採認標準
295	5 General I (QS/RM)	ASME	V&V 10-2019	2019	Standard for Verification and Validation in Computational Solid	113 年度新增採

	通用(品質管理系統/風險管理)				Mechanics	認標準
296	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	/TR 60878 Ed. 4.0 2022-11	2022	Graphical symbols for electrical equipment in medical practice	113 年度新增採認標準
297	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ASTM	D4332-22	2022	Standard Practice for Conditioning Containers Packages or Packaging Components for Testing	113 年度新增採認標準
298	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	20417 First edition 2021-04 Corrected version 2021-12	2021	Medical devices - Information to be supplied by the manufacturer	113 年度新增採認標準
299	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	TIR66: 2017/(R)2020	2020	Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms	113 年度新增採認標準
300	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ASME	V&V 20-2009 (R2021)	2021	Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer	113 年度新增採認標準
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	ISO	ISO 8536-5	2004	Infusion Equipment for Medical Use - Part 5: Burette Type Infusion Sets	原採認標準
302	6 General Plastic	CNS	CNS 14775	2022	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	原採認標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				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	
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	ISO	ISO 11608-4	2022	Pen-injectors for medical use – Part 4:Requirements and test methods for electronic and electromechanical pen-injectors	原採認標準
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	ISO	ISO 21649	2006	Needle-free injectors for medical use –Requirements and test methods	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	ISO	ISO 8362-3	2001	Injection containers and accessories -- Part 3: Aluminium caps for injection vials	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	ISO	ISO 8362-7	2006	Injection containers and accessories –Part 7: Injection caps made of aluminiumplastics combinations without overlapping plastics part	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	CNS	CNS 4397	1999	脫脂紗布	原採認標準版本更新
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	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
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	CNS	CNS 13460	1994	電刀裝置	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	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
311	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫	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

	院及個人使用裝置					
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	ISO	ISO 15883-2	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
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	ISO	ISO 15883-3	2006	Washer-disinfectors -- Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	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	ISO	ISO 15883-5	2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	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	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
316	6 General Plastic Surgery/General Hospital 一般及整	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

	形外科手術/一般醫院及個人使用裝置					
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	CNS	CNS 15044	2007	體溫計探針護套	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	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
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	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
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	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
321	6 General Plastic Surgery/General	CNS	CNS 15226	2009	單次使用之無菌橡膠手套－規格	原採認標準

	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	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
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	ISO	ISO 8536-2	2010	Infusion equipment for medical use -- Part 2: Closures for infusion bottles	原採認標準
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	ISO	ISO 8536-3	2009	Infusion equipment for medical use -- Part 3: Aluminium caps for infusion bottles	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	ISO	ISO 8536-7	2009	Infusion equipment for medical use -- Part 7: Caps made of aluminium-plastics combinations for infusion bottles	原採認標準
326	6 General Plastic	ISO	ISO 8362-6	2010	Injection containers and accessories -- Part 6: Caps made of	原採認標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				aluminium-plastics combinations for injection vials	
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	OIML	OIML R115	2010	Clinical electrical thermometers with maximum device	原採認標準
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	AAMI	AAMI PB70	2012	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	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	ASTM	ASTM F1671/F1671M	2022	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
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	ASTM	ASTM F2172	2022	Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers	原採認標準

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	ASTM	ASTM F86	2021	Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	原採認標準
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	CEN	EN 13726-1	2003	Test methods for primary wound dressings - Part 1: Aspects of absorbency	原採認標準
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	CNS	CNS 14755	2022	拋棄式防塵口罩 (Disposable dust respirators)	原採認標準
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	CNS	CNS 14778	2003	防護衣詞彙 (Terminology relating to protective clothing) (IDE ASTM F1494-01)	原採認標準
335	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫	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

	院及個人使用裝置					
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	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
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	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
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	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
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	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
340	6 General Plastic Surgery/General Hospital 一般及整	IEC	IEC 60601-2-24	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

	形外科手術/一般醫院及個人使用裝置					
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	IEC	IEC 60601-2-41	2021	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
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	ISO	ISO 10555-3	2013	Intravascular catheters -- Sterile and single-use catheters -- Part 3: Central venous catheters	原採認標準
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	ISO	ISO 10555-5	2013	Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters	原採認標準
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	ISO	ISO 11608-2	2022	Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles	原採認標準
345	6 General Plastic Surgery/General	ISO	ISO 11608-3	2012	Needle-based injection systems for medical use -- Requirements and test methods -- Part 3: Finished containers	原採認標準

	Hospital 一般及整形外科手術/一般醫院及個人使用裝置					
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	ISO	ISO 7740	1985	Instruments for surgery, scalpels with detachable blades, fitting dimensions	原採認標準
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	ISO	ISO 8362-4	2011	Injection containers and accessories -- Part 4: Injection vials made of moulded glass	原採認標準
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	ISO	ISO 8536-1	2011	Infusion equipment for medical use — Part 1: Infusion glass bottles - Fourth Edition	原採認標準
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	ISO	ISO 9187-1	2010	Injection equipment for medical use -- Part 1: Ampoules for injectables	原採認標準
350	6 General Plastic	ISO	ISO 10282	2014	Single-use sterile rubber surgical gloves - Specification - Third	原採認標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				Edition	
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	ASTM	ASTM D7160	2016	Standard Practice for Determination of Expiration Dating for Medical Gloves	原採認標準
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	ASTM	ASTM D7161	2016	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions	原採認標準
353	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	ASTM	ASTM F2051	2021	Standard Specification for Implantable Saline Filled Breast Prosthesis	原採認標準
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	EN	EN 1865-1	2015	Patient handling equipment used in road ambulances Part 1: General stretcher systems and patient handling equipmen	原採認標準

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	EN	EN 1865-2	2015	Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher	原採認標準
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	EN	EN 1865-3	2015	Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	原採認標準
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	EN	EN 455-2	2015	Medical gloves for single use. Requirements and testing for physical properties	原採認標準
358	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	EN	EN 455-3	2015	Medical gloves for single use. Requirements and testing for biological evaluation	原採認標準
359	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫	IEC	IEC 60601-2-20	2020	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	原採認標準

	院及個人使用裝置					
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	IEC	IEC 60601-2-21	2020	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	原採認標準
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	IEC	IEC 60601-2-46	2016	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables	原採認標準
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	IEC	IEC 60601-2-50	2020	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	原採認標準
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	IEC	IEC 60601-2-52	2015	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	原採認標準
364	6 General Plastic Surgery/General Hospital 一般及整	IEC	IEC 60601-2-35	2020	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in	原採認標準

	形外科手術/一般醫院及個人使用裝置				medical use	
365	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	ISO	ISO 1135-4	2015	Transfusion equipment for medical use Part 4: Transfusion sets for single use, gravity feed	原採認標準
366	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	ISO	ISO 11608-5	2022	Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions	原採認標準
367	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	ISO	ISO 15883-1	2014	Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests	原採認標準
368	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	ISO	ISO 3826-4	2015	Plastics collapsible containers for human blood and blood components Part 4: Aphaeresis blood bag systems with integrated features	原採認標準
369	6 General Plastic Surgery/General	ISO	ISO 6009	2016	Hypodermic needles for single use - Colour coding for identification	原採認標準

	Hospital 一般及整形外科手術/一般醫院及個人使用裝置					
370	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	ISO	ISO 7864	2016	Sterile hypodermic needles for single use — Requirements and test methods	原採認標準
371	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	ISO	ISO 80369-20	2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	原採認標準
372	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	ISO	ISO 8362-2	2015	Injection containers and accessories - Part 2: Closures for injection vials	原採認標準
373	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	ISO	ISO 8362-5	2016	Injection containers and accessories - Part 5: Freeze drying closures for injection vials	原採認標準
374	6 General Plastic	ISO	ISO 8536-10	2015	Infusion equipment for medical use - Part 10: Accessories for	原採認標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				fluid lines for single use with pressure infusion equipment (ISO 8536-10:2015)	
375	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	ISO	ISO 8536-11	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
376	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	ISO	ISO 8536-6	2016	Infusion equipment for medical use - Part 6: Freeze drying closures for infusion bottles	原採認標準
377	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	ISO	ISO 8536-8	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
378	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	ISO	ISO 8536-9	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

379	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	ISO	ISO 8537	2016	Sterile single-use syringes, with or without needle, for insulin	原採認標準
380	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	ISO	ISO 9626	2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	原採認標準
381	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	ASTM	ASTM F703	2021	Standard Specification for Implantable Breast Prostheses	原採認標準
382	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	CNS	CNS 14774	2022	醫用面(口)罩	原採認標準
383	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫	IEC	IEC 60601-2-19	2020	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	原採認標準

	院及個人使用裝置					
384	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	IEC	IEC 80601-2-59	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
385	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	ISO	ISO 10555-1	2017	Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements	原採認標準
386	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	ISO	ISO 7886-1	2017	Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use	原採認標準
387	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	ISO	ISO 21171	2006	Medical gloves Determination of removable surface powder	原採認標準
388	6 General Plastic Surgery/General Hospital 一般及整	ASTM	ASTM F881	2016	Standard Specification for Silicone Elastomer Facial Implants	原採認標準

	形外科手術/一般醫院及個人使用裝置					
389	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	ASTM	ASTM F1441	2016	Standard Specification for Soft-Tissue Expander Devices	原採認標準
390	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	ASTM	ASTM F754	2015	Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders	原採認標準
391	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	ASTM	ASTM E1104	2023	Standard Specification for Clinical Thermometer Probe Covers and Sheaths	原採認標準
392	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	ASTM	ASTM E1965	2023	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	原採認標準
393	6 General Plastic Surgery/General	AAMI	AAMI BP22	2016	Blood pressure transducers	原採認標準

	Hospital 一般及整形外科手術/一般醫院及個人使用裝置					
394	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	ASTM	ASTM D6124	2022	Standard Test Method for Residual Powder on Medical Gloves	原採認標準
395	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	ASTM	ASTM D6355	2022	Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves	原採認標準
396	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	ASTM	ASTM E1112	2018	Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature	原採認標準
397	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	ISO	ISO 80601-2-56	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
398	6 General Plastic	ASTM	ASTM F1670 /	2017	Standard Test Method for Resistance of Materials Used in	原採認標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置		F1670M		Protective Clothing to Penetration by Synthetic Blood	
399	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	ISO	ISO 11193-1	2020	Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution	原採認標準
400	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	CEN	EN 13795-1	2019	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	原採認標準
401	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	CEN	EN 13795-2	2019	Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits	原採認標準
402	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	ASTM	ASTM F1580	2019	Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants	原採認標準

403	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	ASTM	ASTM F2213	2017	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	原採認標準
404	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	ASTM	ASTM F75	2018	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	原採認標準
405	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	ASTM	ASTM D6499	2018	Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	原採認標準
406	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	ASTM	ASTM D7169	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	原採認標準
407	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫	EN	EN 14683	2019	Medical face masks - Requirements and test methods	原採認標準

	院及個人使用裝置					
408	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	ISO	ISO 8362-1	2018	Injection containers and accessories - Part 1: Injection vials made of glass tubing	原採認標準
409	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	ISO	ISO 7886-2	2020	Sterile Hypodermic Syringes for Single Use - Part 2: Syringes for use with Power-Driven Syringe Pumps	原採認標準
410	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	ISO	ISO 7886-3	2020	Sterile hypodermic syringes for single use -- Part 3: Auto-disable syringes for fixed-dose immunization	原採認標準
411	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	CEN	EN 455-1	2020	Medical gloves for single use —Part 1: Requirements and testing for freedom from holes	原採認標準
412	6 General Plastic Surgery/General Hospital 一般及整	ASTM	ASTM D3577	2019	Standard Specification for Rubber Surgical Gloves	原採認標準

	形外科手術/一般醫院及個人使用裝置					
413	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	ASTM	ASTM D3578	2019	Standard Specification for Rubber Examination Gloves	原採認標準
414	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	ASTM	ASTM D5151	2019	Standard Test Method for Detection of Holes in Medical Gloves	原採認標準
415	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	ASTM	ASTM D6978	2019	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	原採認標準
416	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	ASTM	ASTM F2182	2020	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	原採認標準
417	6 General Plastic Surgery/General	ASTM	ASTM F2503	2020	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	原採認標準

	Hospital 一般及整形外科手術/一般醫院及個人使用裝置					
418	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	ASTM	ASTM F899	2020	Standard Specification for Wrought Stainless Steels for Surgical Instruments	原採認標準
419	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	ISO	ISO 8536-4	2019	Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed	原採認標準
420	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	ASTM	ASTM A908	2019	Standard Specification for Stainless Steel Needle Tubing	原採認標準
421	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	ASTM	ASTM D5250	2019	Standard Specification for Poly(vinyl chloride) Gloves for Medical Application	原採認標準
422	6 General Plastic	ASTM	ASTM F2710	2019	Standard Consumer Safety Performance Specification for	原採認標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				Commercial Cribs	
423	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	ASTM	ASTM D6319	2019	Standard Specification for Nitrile Examination Gloves for Medical Application	原採認標準
424	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	ASTM	D6977	2019	Standard Specification for Polychloroprene Examination Gloves for Medical Application	原採認標準
425	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	ASTM	D7103	2019	Standard Guide for Assessment of Medical Gloves	原採認標準
426	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	AAMI	AAMI TIR38	2019	Medical device safety assurance case guidance	原採認標準

427	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	EN ISO	EN ISO 15747	2019	Plastic containers for intravenous injections	原採認標準
428	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	ASTM	ASTM F2407	2020	Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	原採認標準
429	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	ISO	ISO 22610	2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration	原採認標準
430	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	AAMI	AAMI TIR101	2021	Fluid delivery performance testing for infusion pumps	原採認標準
431	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫	ISO	ISO 11608-1	2022	Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems	原採認標準

	院及個人使用裝置					
432	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	ISO	ISO 11040-4	2020	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling [Including AMENDMENT 1 (2020)]	原採認標準
433	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	ASTM	ASTM F3352	2019	Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities	原採認標準
434	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	ISO	ISO 11608-6	2022	Needle-based injection systems for medical use - Requirements and test methods - Part 6: On-body delivery	原採認標準
435	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	ANSI AAMI	ANSI AAMI CN27	2021	General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications	原採認標準
436	6 General Plastic Surgery/General Hospital 一般及整	ASTM	F2100-23	2023	Standard Specification for Performance of Materials Used in Medical Face Masks	113 年度新增採認標準

	形外科手術/一般醫院及個人使用裝置					
437	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	ASTM	F1671/F1671M-22	2022	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	113 年度新增採認標準
438	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	ANSI AAMI	PB70:2022	2022	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	113 年度新增採認標準
439	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	IEC	60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION	2015	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	113 年度新增採認標準
440	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	ASTM	F739-20	2020	Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact	113 年度新增採認標準
441	6 General Plastic Surgery/General	IEC	60601-2-35 Edition 2.0	2020	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices	113 年度新增採認標準

	Hospital 一般及整形外科手術/一般醫院及個人使用裝置		2020-09		using blankets pads and mattresses and intended for heating in medical use	
442	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	ASTM	F1670/F1670M-17a	2017	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	113 年度新增採認標準
443	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	ISO	7886-4 Second Edition 2018-11	2018	Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature	113 年度新增採認標準
444	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	ASTM	F2101-23	2023	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials Using a Biological Aerosol of Staphylococcus aureus	113 年度新增採認標準
445	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	ASTM	F3352/F3352M-23a	2023	Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities	113 年度新增採認標準
446	6 General Plastic	ISO	10555-6 First	2015	Intravascular catheters - Sterile and single-use catheters - Part 6:	113 年度新增採

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置		edition 2015-04-15 [Including AMD1:2019]		Subcutaneous implanted ports [Including AMENDMENT 1 (2019)]	認標準
447	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	ISO	ISO 20698 First Edition 2018-07	2018	Catheter systems for neuraxial application - Sterile and single-use catheters and accessories	113 年度新增採認標準
448	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	ASTM	F3502-22a	2022	Standard Specification for Barrier Face Coverings	113 年度新增採認標準
449	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	ISO	10535 Third edition 2021-10	2021	Assistive products - Hoists for the transfer of disabled persons - Requirements and test methods	113 年度新增採認標準
450	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS GP14-A	1996	Labeling of Home-Use In Vitro Testing Products; Approved Guideline	原採認標準
451	7 In Vitro Diagnostics 體外	CLSI	H15-A3	2000	Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard -	原採認標準

	診斷醫療器材				Third Edition	
452	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M15-A	2000	Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline	原採認標準
453	7 In Vitro Diagnostics 體外診斷醫療器材	CEN	EN 13612	2002	Performance evaluation of in vitro diagnostic medical devices	原採認標準
454	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18153	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
455	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H56-A	2006	Body fluid analysis for cellular composition	原採認標準
456	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA02-A2	2006	Quality assurance of laboratory tests for autoantibodies to nuclear antigens: (1)Indirect fluorescence assay for microscopy and (2) Microtiter enzyme immunoassay methods	原採認標準
457	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C39-A	2000	A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard	原採認標準
458	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C44-A	2002	Harmonization of Glycohemoglobin Measurements; Approved Guideline	原採認標準
459	7 In Vitro	CLSI	C45-A	2004	Measurement of Free Thyroid Hormones; - Approved Guideline	原採認標準

	Diagnostics 體外診斷醫療器材					
460	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H45-A2	2005	Performance of the Bleeding Time Test; Approved Guideline	原採認標準
461	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	POCT01-A2	2006	Point-of-Care Connectivity; Approved Standard- Second Edition	原採認標準
462	7 In Vitro Diagnostics 體外診斷醫療器材	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
463	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP06 Ed2	2020	Evaluation of the Linearity of Quantitative Measurement Procedures	原採認標準
464	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M26-A	1999	Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline	原採認標準
465	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM13-A	2006	Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline	原採認標準
466	7 In Vitro Diagnostics 體外診斷醫療器材	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
467	7 In Vitro	CLSI	I/LA21-A2	2008	Clinical Evaluation of Immunoassays; Approved	原採認標準

	Diagnostics 體外診斷醫療器材				Guideline-Second Edition	
468	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H20-A2	2007	Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition	原採認標準
469	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H42-A2	2007	Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline - Second Edition	原採認標準
470	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H43-A2	2007	Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline - Second Edition	原採認標準
471	7 In Vitro Diagnostics 體外診斷醫療器材	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
472	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA18-A2	2001	Specifications for Immunological Testing for Infectious Diseases; Approved Guideline - Second Edition	原採認標準
473	7 In Vitro Diagnostics 體外診斷醫療器材	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
474	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP12-A2	2008	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition	原採認標準
475	7 In Vitro	CLSI	EP18-A2	2009	Risk Management Techniques to Identify and Control Laboratory	原採認標準

	Diagnostics 體外診斷醫療器材				Error Sources; Approved Guideline-Second Edition	
476	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP16-A3	2009	Urinalysis; Approved Guideline - Third Edition	原採認標準
477	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C46-A2	2009	Blood Gas and pH Analysis and Related Measurements; Approved Guideline-Second Edition	原採認標準
478	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H26-A2	2010	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard-Second Edition	原採認標準
479	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M22-A3	2004	Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard- Third Edition (2004)	原採認標準
480	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM11-A	2007	Molecular Methods for Bacterial Strain Typing; Approved Guideline	原採認標準
481	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C43-A2	2010	Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline-Second Edition	原採認標準
482	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H54-A	2005	Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline	原採認標準
483	7 In Vitro	CLSI	H57-A	2008	Protocol for the Evaluation, Validation, and Implementation of	原採認標準

	Diagnostics 體外診斷醫療器材				Coagulometers; Approved Guideline	
484	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA29-A	2008	Detection of HLA-Specific Alloantibody by Flow Cytometry and Solid Phase Assays; Approved Guideline	原採認標準
485	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP25-A	2009	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline	原採認標準
486	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C61-A	1998	Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard	原採認標準
487	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C40-A2	2013	Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline	原採認標準
488	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP17-A2	2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition	原採認標準
489	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP40-A4-AMD	2012	Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline, Fourth Edition	原採認標準
490	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP42-A6	2008	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard--Sixth Edition	原採認標準
491	7 In Vitro	CLSI	M39-A4	2014	Analysis and Presentation of Cumulative Antimicrobial	原採認標準

	Diagnostics 體外診斷醫療器材				Susceptibility Test Data; Approved Guideline - Fourth Edition; Vol. 34; No. 2	
492	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM09-A2	2014	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline	原採認標準
493	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP10-A3-AMD	2019	Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline - Third Edition	原採認標準
494	7 In Vitro Diagnostics 體外診斷醫療器材	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
495	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP28-A3C	2010	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition	原採認標準
496	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP39-A6	2010	Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition	原採認標準
497	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA25-A2	2011	Maternal Serum Screening; Approved Standard, Second Edition	原採認標準
498	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM01-A3	2012	Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline	原採認標準
499	7 In Vitro	CLSI	MM05-A2	2012	Nucleic Acid Amplification Assays for Molecular	原採認標準

	Diagnostics 體外診斷醫療器材				Hematopathology; Approved Guideline-Second Edition,MM05A2E	
500	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM06-A2	2010	Quantitative Molecular Methods for Infectious Diseases; Approved Guideline - Second Edition	原採認標準
501	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM14-A2	2013	Design of Molecular Proficiency Testing/External Quality Assessment; Approved Guideline—Second Edition	原採認標準
502	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	POCT12-A3	2013	Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline, Third Edition,	原採認標準
503	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT14	2020	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline	原採認標準
504	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	QMS06-A3	2018	Quality Management System: Continual Improvement; Approved Guideline - Third Edition; Vol 31; No 14	原採認標準
505	7 In Vitro Diagnostics 體外診斷醫療器材	CNS	CNS 15449-2-101	2014	量測、控制及實驗室使用電氣設備安全規定－第 2-101 部:體外診斷(IVD)醫用設備之個別規定 Safe requirements for electrical for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IDT: IEC 61010-2-101:2002)	原採認標準
506	7 In Vitro Diagnostics 體外	CLSI	GP34-A	2010	Validation and Verfication of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guidance	原採認標準

	診斷醫療器材					
507	7 In Vitro Diagnostics 體外診斷醫療器材	EN	EN 13532	2002	General requirements for in vitro diagnostic medical devices for self-testing	原採認標準
508	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61326-2-6	2020	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
509	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 15193	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
510	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 15194	2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation - Second Edition	原採認標準
511	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 15197	2013	In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	原採認標準
512	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-1	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
513	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-2	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

514	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-3	2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use - First Edition	原採認標準
515	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-4	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
516	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-5	2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing - First Edition	原採認標準
517	7 In Vitro Diagnostics 體外診斷醫療器材	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
518	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C24	2016	Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions	原採認標準
519	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C62-A	2014	Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline - Vol 34; No 16	原採認標準
520	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP05-A3	2014	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline	原採認標準
521	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP14-A3	2014	Evaluation of Matrix Effects; Approved Guideline	原採認標準

522	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP15-A3	2019	User Verification of Performance for Precision and Trueness	原採認標準
523	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP19	2020	A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures - Second Edition; Vol 35; No 10	原採認標準
524	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP21	2016	Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures	原採認標準
525	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA20Ed3	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
526	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM03	2015	Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline	原採認標準
527	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM21	2015	Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications	原採認標準
528	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	POCT04	2016	Essential Tools for Implementation and Management of a Point-of-Care Testing Program - Third Edition	原採認標準
529	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	POCT13	2018	Glucose Monitoring in Settings Without Laboratory Support	原採認標準

530	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 22870	2016	Point-of-care testing (POCT) - Requirements for quality and competence	原採認標準
531	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 17822	2020	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
532	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C49	2018	Analysis of Body Fluids in Clinical Chemistry; Approved Guideline	原採認標準
533	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP09c	2018	Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition	原採認標準
534	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M27	2017	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement	原採認標準
535	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	VET01	2020	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals	原採認標準
536	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP07	2018	Interference Testing in Clinical Chemistry	原採認標準
537	7 In Vitro Diagnostics 體外	CLSI	M23	2018	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters	原採認標準

	診斷醫療器材					
538	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M02	2018	Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard -Twelfth Edition	原採認標準
539	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M07	2018	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard -Tenth Edition	原採認標準
540	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M11	2018	Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard	原採認標準
541	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M24	2018	Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard	原採認標準
542	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 6710	2017	Single-use containers for human venous blood specimen collection	原採認標準
543	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M45	2016	Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline	原採認標準
544	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61010-2-101	2018	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101: Particular Requirements for in Vitro Diagnostic (IVD) Medical Equipment	原採認標準
545	7 In Vitro Diagnostics 體外	CLSI	QMS24	2016	Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality	原採認標準

	診斷醫療器材					
546	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM17	2018	Validation and Verification of Multiplex Nucleic Acid Assays	原採認標準
547	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM23	2015	Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms)	原採認標準
548	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 17511	2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	原採認標準
549	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 20776-1	2019	Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases	原採認標準
550	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61010-1	2019	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements	原採認標準
551	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO/TS 20914	2019	Medical laboratories - Practical guidance for the estimation of measurement uncertainty	原採認標準
552	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP35	2019	Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures-1st Edition	原採認標準

553	7 In Vitro Diagnostics 體外診斷醫療器材	CEN ISO	EN ISO 23640	2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents	原採認標準
554	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M36-A	2004	Clinical Use and Interpretation of Serologic Tests for Toxoplasma gondii, 1st Edition	原採認標準
555	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M62 1st	2020	Performance Standards for Susceptibility Testing of Mycobacteria Nocardia spp. and other Aerobic Actinomycetes	原採認標準
556	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT05	2020	Performance Metrics for Continuous Interstitial Glucose Monitoring	原採認標準
557	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 17099	2014	Radiological protection - Performance criteria for laboratories using the cytokinesis block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry	原採認標準
558	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP39	2021	A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests	原採認標準
559	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M60	2020	Performance Standards for Antifungal Susceptibility Testing of Yeast	原採認標準
560	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 19238	2014	Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics	原採認標準

561	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M39 5th	2022	Analysis and presentation of cumulative antimicrobial susceptibility test data	原採認標準
562	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	17511 Second	2020	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	原採認標準
563	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP25-A (Replaces EP25-P)	2013	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.	113 年度新增採認標準
564	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M100 33rd Edition	2023	Performance Standards for Antimicrobial Susceptibility Testing	113 年度新增採認標準
565	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP12 3rd Edition	2023	Evaluation of Qualitative Binary Output Examination Performance	113 年度新增採認標準
566	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NBS01 7th Edition	2021	Dried Blood Spot Specimen Collection for Newborn Screening	113 年度新增採認標準
567	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP27 2nd Edition	2022	Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures	113 年度新增採認標準
568	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M27M44S 3rd Edition	2022	Performance Standards for Antifungal Susceptibility Testing of Yeasts	113 年度新增採認標準

569	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP06-A(2003)	2003	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline	113 年度新增採認標準
570	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H47-A2	2008	One-Stage Prothrombin Time (PT) Test And Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline - Second Edition	113 年度新增採認標準
571	8 Materials 材料	ISO	ISO 5832-6	1997	Implants for surgery -- Metallic materials -- Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	原採認標準
572	8 Materials 材料	ISO	ISO 5832-5	2022	Implants for surgery -- Metallic materials -- Part 5: Wrought cobalt-chromium-tungsten-nickel alloy	原採認標準
573	8 Materials 材料	ISO	ISO 16428	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
574	8 Materials 材料	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
575	8 Materials 材料	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
576	8 Materials 材料	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
577	8 Materials 材料	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
578	8 Materials 材料	CNS	CNS 13382-5	2004	外科體內植入物－金屬材料－鈦金屬	原採認標準
579	8 Materials 材料	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
580	8 Materials 材料	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
581	8 Materials 材料	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
582	8 Materials 材料	CEN	EN 29073-3	1992	Textiles — Test methods for nonwovens — Part 3:	原採認標準

					Determination of tensile strength and elongation	
583	8 Materials 材料	ISO	ISO 9073-10	2003	Textiles -- Test methods for nonwovens -- Part 10: Lint and other particles generation in the dry state	原採認標準
584	8 Materials 材料	ASTM	ASTM F1713	2021	Standard Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130)	原採認標準
585	8 Materials 材料	ASTM	ASTM F562	2022	Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)	原採認標準
586	8 Materials 材料	ISO	ISO 139	2011	Textiles -- Standard atmospheres for conditioning and testing	原採認標準
587	8 Materials 材料	ASTM	ASTM D3772	2021	Standard Specification for Industrial Rubber Finger Cots	原採認標準
588	8 Materials 材料	ASTM	ASTM F1185	2014	Standard Specification for Composition of Hydroxylapatite for Surgical Implants	原採認標準
589	8 Materials 材料	ASTM	ASTM F136	2021	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	原採認標準
590	8 Materials 材料	ASTM	ASTM F2224	2020	Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants	原採認標準
591	8 Materials 材料	ASTM	ASTM F2347	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
592	8 Materials 材料	ASTM	ASTM F2565	2021	Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications	原採認標準

593	8 Materials 材料	ASTM	ASTM F2695	2020	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
594	8 Materials 材料	ASTM	ASTM F2820	2021	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	原採認標準
595	8 Materials 材料	ASTM	ASTM F2971	2021	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing	原採認標準
596	8 Materials 材料	ASTM	ASTM F3087	2015	Standard Specification for Acrylic Molding Resins for Medical Implant Applications	原採認標準
597	8 Materials 材料	ISO	ISO 13356	2015	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia (Y–TZP).	原採認標準
598	8 Materials 材料	ISO	ISO 14708-1	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
599	8 Materials 材料	ISO	ISO 5832-1	2016	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel	原採認標準
600	8 Materials 材料	ISO	ISO 5832-11	2014	Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy	原採認標準
601	8 Materials 材料	ISO	ISO 5832-3	2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	原採認標準
602	8 Materials 材料	ISO	ISO 5832-4	2014	Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy - Third Edition	原採認標準
603	8 Materials 材料	ISO	ISO 5832-7	2016	Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobaltchromium- nickel-molybdenum-iron alloy	原採認標準

604	8 Materials 材料	ISO	ISO/ASTM 52900	2015	Standard Terminology for Additive Manufacturing – General Principles – Terminology	原採認標準
605	8 Materials 材料	ISO	ISO/ASTM 52921	2013	Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies	原採認標準
606	8 Materials 材料	ASTM	ASTM D412	2021	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension	原採認標準
607	8 Materials 材料	ASTM	ASTM F1925	2022	Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants	原採認標準
608	8 Materials 材料	ASTM	ASTM F2026	2017	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	原採認標準
609	8 Materials 材料	ASTM	ASTM F2052	2021	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	原採認標準
610	8 Materials 材料	ASTM	ASTM F2459	2018	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis	原採認標準
611	8 Materials 材料	ISO	ISO 10974	2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	原採認標準
612	8 Materials 材料	ISO	ISO 5832-2	2018	Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium	原採認標準
613	8 Materials 材料	ISO	ISO/ASTM 52901	2017	Standard Guide for Additive Manufacturing—General Principles—Requirements for Purchased AM Parts	原採認標準
614	8 Materials 材料	AAMI	AAMI ST65	2018	Processing of reusable surgical textiles for use in health care facilities	原採認標準
615	8 Materials 材料	ASTM	ASTM F2393	2020	Standard Specification for High-Purity Dense Magnesia Partially	原採認標準

					Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications	
616	8 Materials 材料	ASTM	ASTM F621	2021	Standard Specification for Stainless Steel Forgings for Surgical Implants	原採認標準
617	8 Materials 材料	ASTM	ASTM F1581	2020	Standard Specification for Composition of Anorganic Bone for Surgical Implants	原採認標準
618	8 Materials 材料	ASTM	ASTM F3260	2018	Standard Test Method for Determining the Flexural Stiffness of Medical Textiles	原採認標準
619	8 Materials 材料	ISO	ISO 5834-3	2019	Implants for surgery – Ultra-high molecular-weight polyethylene – Part 3:Accelerated ageing methods	原採認標準
620	8 Materials 材料	ISO	ISO 5834-4	2019	Implants for surgery – Ultra-high molecular-weight polyethylene – Part 4:Oxidation index measurement method	原採認標準
621	8 Materials 材料	ISO	ISO 5834-5	2019	Implants for surgery – Ultra-high molecular-weight polyethylene – Part 5:Morphology assessment method	原採認標準
622	8 Materials 材料	ISO	ISO 5832-9	2019	Implants for surgery -- Metallic materials -- Part 9:Wrought high nitrogen stainless steel	原採認標準
623	8 Materials 材料	ISO	ISO 5832-12	2019	Implants for surgery -- Metallic materials -- Part 12:Wrought cobalt-chromium-molybdenum alloy	原採認標準
624	8 Materials 材料	ISO	ISO 5834-1	2019	Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 1:Powder form	原採認標準
625	8 Materials 材料	ISO	ISO 6474-1	2019	Implants for surgery -- Ceramic materials -- Part 1:Ceramic materials based on high purity alumina	原採認標準
626	8 Materials 材料	ISO	ISO 811	2018	Textiles - Determination of resistance to water penetration - Hydrostatic pressure test	原採認標準
627	8 Materials 材料	ASTM	ASTM F2063	2018	Standard Specification for Wrought Nickel-Titanium Shape	原採認標準

					Memory Alloys for Medical Devices and Surgical Implants	
628	8 Materials 材料	ISO	ISO 5834-2	2019	Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 2: Moulded forms	原採認標準
629	8 Materials 材料	ASTM	ASTM F2313	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	原採認標準
630	8 Materials 材料	ASTM	ASTM F3268	2018	Standard Guide for in vitro Degradation Testing of Absorbable Metals	原採認標準
631	8 Materials 材料	ISO	ISO/ASTM 52910-18	2018	Additive manufacturing - Design - Requirements, guidelines and recommendations	原採認標準
632	8 Materials 材料	ASTM	ASTM F3301	2018	Standard for Additive Manufacturing—Post Processing Methods—Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion.	原採認標準
633	8 Materials 材料	ASTM	ASTM F3302	2018	Standard for Additive Manufacturing—Finished Part Properties—Standard Specification for Titanium Alloys via Powder Bed Fusion	原採認標準
634	8 Materials 材料	ISO/ASTM	ISO/ASTM 52904	2019	Standard for Additive Manufacturing—Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications.	原採認標準
635	8 Materials 材料	ISO	ISO 13782	2019	Implants for surgery -- Metallic materials -- Unalloyed tantalum for surgical implant applications	原採認標準
636	8 Materials 材料	ISO	ISO 13938-1	2019	Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension	原採認標準

637	8 Materials 材料	ASTM	ASTM F1091	2020	Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605)	原採認標準
638	8 Materials 材料	ASTM	ASTM F139	2019	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	原採認標準
639	8 Materials 材料	ASTM	ASTM F1537	2020	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	原採認標準
640	8 Materials 材料	ASTM	ASTM F2129	2019	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	原採認標準
641	8 Materials 材料	ASTM	ASTM F3208	2020	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices	原採認標準
642	8 Materials 材料	ASTM	D638	2022	Standard Test Method for Tensile Properties of Plastics	原採認標準
643	8 Materials 材料	ASTM	E647	2022	Standard Test Method for Measurement of Fatigue Crack Growth Rates	原採認標準
644	8 Materials 材料	ASTM	F2633	2019	Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants	原採認標準
645	8 Materials 材料	ASTM	F3321	2019	Standard Guide for Methods of Extraction of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices	原採認標準
646	8 Materials 材料	ASTM ISO	ISO/ASTM 52907	2019	Additive Manufacturing - Feedstock materials - Methods to characterize metal powders	原採認標準

647	8 Materials 材料	ASTM ISO	ISO/ASTM 52911-1	2019	Additive Manufacturing - Design - Part 1: Laser-based powder bed fusion of metals	原採認標準
648	8 Materials 材料	ASTM ISO	ISO/ASTM 52911-2	2019	Additive Manufacturing - Design - Part 2: Laser-based powder bed fusion of polymers	原採認標準
649	8 Materials 材料	ASTM ISO	ISO/ASTM 52902	2019	Additive Manufacturing -Test Artifacts - Geometric capability assessment of additive manufacturing systems	原採認標準
650	8 Materials 材料	ASTM	F3335	2020	Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion	原採認標準
651	8 Materials 材料	ASTM ISO	ASTM ISO 52915	2020	Specification for additive manufacturing file format (AMF) Version 1.2	原採認標準
652	8 Materials 材料	ASTM	ASTM F2181	2020	Standard Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants	原採認標準
653	8 Materials 材料	ASTM ISO	ASTM ISO TR 52912	2020	Additive manufacturing - Design - Functionally graded additive manufacturing	原採認標準
654	8 Materials 材料	ASTM	ASTM F620	2020	Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition	原採認標準
655	8 Materials 材料	ASTM	ASTM F2977	2020	Standard Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants	原採認標準
656	8 Materials 材料	ASTM	ASTM F3044	2020	Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants	原採認標準
657	8 Materials 材料	ASTM	ASTM F629	2020	Standard Practice for Radiography of Cast Metallic Surgical Implants	原採認標準
658	8 Materials 材料	ASTM	ASTM F961	2020	Standard Specification for	原採認標準

					35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)	
659	8 Materials 材料	ASTM	ASTM F3434	2020	Guide for Additive manufacturing - Installation/Operation and Performance Qualification (IQ/OQ/PQ) of Laser-Beam Powder Bed Fusion Equipment for Production Manufacturing	原採認標準
660	8 Materials 材料	ASTM	ASTM F2895	2020	Standard Practice for Digital Radiography of Cast Metallic Implants	原採認標準
661	8 Materials 材料	ASTM ISO	ASTM ISO 52903-1	2020	Additive manufacturing - Material extrusion-based additive manufacturing of plastic materials - Part 1: Feedstock materials	原採認標準
662	8 Materials 材料	ASTM	ASTM F1472	2020	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)	原採認標準
663	8 Materials 材料	ASTM	ASTM F3333	2020	Standard Specification for Chopped Carbon Fiber Reinforced (CFR) Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	原採認標準
664	8 Materials 材料	ASTM	ASTM F640	2020	Standard Test Methods for Determining Radiopacity for Medical Use	原採認標準
665	8 Materials 材料	ASTM	ASTM F67	2017	Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)	原採認標準
666	8 Materials 材料	ASTM	ASTM F2754/F2754M	2021	Standard Test Method for Measurement of Camber, Cast, Helix and Direction of Helix of Coiled Wire	原採認標準
667	8 Materials 材料	ASTM	ASTM F560	2022	Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	原採認標準

668	8 Materials 材料	ASTM	ASTM F648	2021	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	原採認標準
669	8 Materials 材料	ASTM	ASTM F1813	2021	Standard Specification for Wrought Titanium - 12 Molybdenum - 6 Zirconium - 2 Iron Alloy for Surgical Implant (UNS R58120)	原採認標準
670	8 Materials 材料	ASTM	ASTM F1586	2021	Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)	原採認標準
671	8 Materials 材料	ASTM	ASTM F3384	2021	Standard Specification for Polydioxanone Polymer Resins for Surgical Implants	原採認標準
672	8 Materials 材料	ISO	ISO 13779-3	2018	Implants for surgery -- Hydroxyapatite -- Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity [Including AMENDMENT 1 (2021)]	原採認標準
673	8 Materials 材料	IEC	IEC 63145-22-10	2020	Eyewear display -- Part 22-10: Specific measurement methods for AR type -- Optical properties	原採認標準
674	8 Materials 材料	IEC	IEC 63145-20-10	2019	Eyewear display -- Part 20-10: Fundamental measurement methods -- Optical properties	原採認標準
675	8 Materials 材料	IEC	IEC 63145-20-20	2019	Eyewear display -- Part 20-20: Fundamental measurement methods -- Image quality	原採認標準
676	8 Materials 材料	ASTM	ASTM F1108	2021	Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)	原採認標準
677	8 Materials 材料	ASTM	ASTM F2146	2022	Standard Specification for Wrought Titanium-3Aluminum-2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320)	原採認標準
678	8 Materials 材料	ASTM	ASTM F1377	2021	Standard Specification for Cobalt-28Chromium-6Molybdenum	原採認標準

					Powder for Medical Devices (UNS R30075, UNS R31537, and UNS R31538)	
679	8 Materials 材料	ASTM	ASTM F2989	2021	Standard Specification for Metal Injection Molded Unalloyed Titanium Components for Surgical Implant Applications	原採認標準
680	8 Materials 材料	ASTM	ASTM F2229	2021	Standard Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108)	原採認標準
681	8 Materials 材料	ASTM	ASTM F1801	2020	Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials	原採認標準
682	8 Materials 材料	ASTM	ASTM F2005	2021	Standard Terminology for Nickel-Titanium Shape Memory Alloys	原採認標準
683	8 Materials 材料	ISO	ISO 13779-6	2016	Implants for surgery - Hydroxyapatite - Part 6: Powders	原採認標準
684	8 Materials 材料	ISO	ISO 13179-1	2021	Implants for surgery -- Coatings on metallic surgical implants -- Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders	原採認標準
685	8 Materials 材料	ASTM	ASTM F2848	2021	Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns	原採認標準
686	8 Materials 材料	ASTM	ASTM F3160	2021	Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants	原採認標準
687	8 Materials 材料	ASTM	ASTM F2458-05(2015)	2015	Standard Test Method For Wound Closure Strength Of Tissue Adhesives And Sealants	113 年度新增採認標準
688	8 Materials 材料	ASTM	ASTM F2258-05(2015)	2015	Standard Test Method For Strength Properties Of Tissue Adhesives In Tension	113 年度新增採認標準

689	8 Materials 材料	ASTM	ASTM F2256-05(2015)	2015	Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	113 年度新增採認標準
690	8 Materials 材料	ASTM	ASTM F2255-05(2015)	2015	Standard Test Method For Strength Properties Of Tissue Adhesives In Lap-Shear By Tension Loading	113 年度新增採認標準
691	8 Materials 材料	ASTM	ASTM D3654/D3654M 06(2019)	2019	Standard Test Methods For Shear Adhesion Of Pressure-Sensitive Tapes	113 年度新增採認標準
692	8 Materials 材料	ASTM	ASTM D3330/D3330M 04(2018)	2018	Standard Test Method For Peel Adhesion Of Pressure-Sensitive Tape	113 年度新增採認標準
693	8 Materials 材料	ASTM	F2003-02(2022)	2022	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air	113 年度新增採認標準
694	8 Materials 材料	ASTM	F1978-22	2022	Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser	113 年度新增採認標準
695	8 Materials 材料	ASTM	F2503-23	2023	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	113 年度新增採認標準
696	8 Materials 材料	ASTM	F2516-22	2022	Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials	113 年度新增採認標準
697	8 Materials 材料	ASTM	F1472-23	2023	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)	113 年度新增採認標準
698	8 Materials 材料	ASTM	F1295-22	2022	Standard Specification for Wrought Titanium-6 Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)	113 年度新增採認標準

699	8 Materials　材料	ASTM	F3109-22	2022	Standard Test Method for Verification of Multi-Axis Force Measuring Platforms	113 年度新增採認標準
700	8 Materials　材料	ISO	5832-6 Third Edition 2022-03	2022	Implants for surgery -- Metallic materials -- Part 6:Wrought cobalt-nickel-chromium-molybdenum alloy	113 年度新增採認標準
701	8 Materials　材料	ASTM	D412-16(2021)	2021	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension	113 年度新增採認標準
702	8 Materials　材料	ASTM	F2257-22	2022	Standard Specification for Wrought Seamless or Welded and Drawn 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673)	113 年度新增採認標準
703	8 Materials　材料	ISO	5832-5 Fourth Edition 2022-03	2022	Implants for surgery -- Metallic materials -- Part 5: Wrought cobalt-chromium-tungsten-nickel	113 年度新增採認標準
704	9 ObGyn/Gastroenterology　胃腸病科學及泌尿科學/婦產科學	IEC	IEC 60601-2-18	2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	原採認標準
705	9 ObGyn/Gastroenterology　胃腸病科學及泌尿科學/婦產科學	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
706	9 ObGyn/Gastroenterology　胃腸病科學	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

	及泌尿科學/婦產科學					
707	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ASTM	ASTM D1894	2014	Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting	原採認標準
708	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 4074	2015	Natural latex rubber condoms - Requirements and test methods	原採認標準
709	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 7439	2015	Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2015)	原採認標準
710	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8009	2014	Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests	原採認標準
711	9 ObGyn/Gastroentero	ISO	ISO 8637-1	2017	Extracorporeal systems for blood purification -- Part 1: Haemodialysers, haemodiafilters, haemofilters and	原採認標準

	logy 胃腸病科學及泌尿科學/婦產科學				haemoconcentrators	
712	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ASTM	ASTM F1828	2017	Standard Specification for Ureteral Stents	原採認標準
713	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	IEC	IEC 60601-2-16	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
714	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 29943-1	2017	Condoms—Guidance on clinical studies—Part 1: Male condoms, clinical function studies based on self-reports	原採認標準
715	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 29943-2	2017	Condoms—Guidance on clinical studies—Part 2: Female condoms, clinical function studies	原採認標準
716	9	ISO	ISO 8637-2	2018	Extracorporeal systems for blood purification — Part 2:	原採認標準

	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學				Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters	
717	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-3	2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies	原採認標準
718	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-2	2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies	原採認標準
719	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI/ISO 23500-1	2019	Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements	原採認標準
720	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	EN	ISO 20695	2020	Enteral feeding systems — Design and testing	原採認標準

721	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-5	2019	Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies	原採認標準
722	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-4	2019	Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies	原採認標準
723	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8600-3	2019	Endoscopes — Medical endoscopes and endotherapy devices —Part 3: Determination of field of view and direction of view of endoscopes with optics	原採認標準
724	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD47-2020	2020	Reprocessing of hemodialyzers	原採認標準
725	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科	CIE ISO	ISO/CIE 11664-1	2019	Colorimetry - Part 1: CIE standard colorimetric observers	原採認標準

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726	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	CIE ISO	ISO/CIE 11664-3	2019	Colorimetry - Part 3: CIE tristimulus values	原採認標準
727	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	CIE ISO	ISO/CIE 11664-4	2019	Colorimetry - Part 4: CIE 1976 L*a*b* colour space	原採認標準
728	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8600-5	2020	Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics	原採認標準
729	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	CIE ISO	CIE ISO 11664-5	2016	Colorimetry - Part 5: CIE 1976 L*u*v* colour space and u',v' uniform chromaticity scale diagram	原採認標準
730	9 ObGyn/Gastroenterology 胃腸病科學	ISO CIE	11664-2 First edition 2022-08	2022	Colorimetry - Part 2: CIE standard illuminants	113 年度新增採認標準

	及泌尿科學/婦產科學					
731	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO CIE	11664-6 Second edition 2022-08	2022	Colorimetry - Part 6: CIEDE2000 colour-difference formula	113 年度新增採認標準
732	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	IEC	60601-2-39 Edition 3.0 2018-04	2018	Medical electrical equipment Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment	113 年度新增採認標準
733	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	8637-2 First Edition 2018-07	2018	Extracorporeal systems for blood purification - Part 2: Extracorporeal blood circuit for hemodialyzers hemodiafilters and hemofilters	113 年度新增採認標準
734	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	20696 First edition 2018-06; Corrected 2019-12	2018	Sterile urethral catheters for single use	113 年度新增採認標準
735	9 ObGyn/Gastroentero	ASTM	D7661-18	2018	Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms	113 年度新增採認標準

	logy 胃腸病科學及泌尿科學/婦產科學					
736	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ASTM	D1894-14	2014	Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting	113 年度新增採認標準
737	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	8637-3 First Edition 2018-07	2018	Extracorporeal systems for blood purification - Part 3: Plasmafilters	113 年度新增採認標準
738	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	20697 First edition 2018-06; Corrected 2018-09	2018	Sterile drainage catheters and accessory devices for single use	113 年度新增採認標準
739	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	8600-4 Third Edition 2023-01	2023	Endoscopes - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion	113 年度新增採認標準
740	10 Ophthalmic 眼	CNS	CNS 12446	1988	軟性隱形眼鏡片	原採認標準

	科學					
741	10 Ophthalmic 眼科學	ISO	ISO 8980-4	2006	Ophthalmic optics -- Uncut finished spectacle lenses -- Part 4: Specifications and test methods for anti-reflective coatings	原採認標準
742	10 Ophthalmic 眼科學	ISO	ISO 8980-5	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
743	10 Ophthalmic 眼科學	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
744	10 Ophthalmic 眼科學	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
745	10 Ophthalmic 眼科學	ISO	ISO 10936-2	2010	Optics and photonics -- Operation microscopes -- Part 2: Light hazard from operation microscopes used in ocular surgery	原採認標準
746	10 Ophthalmic 眼科學	ISO	ISO 11979-3	2012	Ophthalmic Implants - Intraocular Lenses - Part 3: Mechanical Properties and Test Methods - Third Edition	原採認標準
747	10 Ophthalmic 眼科學	ISO	ISO 11979-5	2020	Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility	原採認標準
748	10 Ophthalmic 眼科學	ISO	ISO 11987	2012	Ophthalmic optics -- Contact lenses -- Determination of shelf-life	原採認標準
749	10 Ophthalmic 眼科學	ISO	ISO 14534	2011	Ophthalmic optics -- Contact lenses and contact lens care products -- Fundamental requirements	原採認標準

750	10 Ophthalmic 眼科學	ISO	ISO 8980-3	2013	Ophthalmic optics -- Uncut finished spectacle lenses -- Part 3: Transmittance specifications and test methods	原採認標準
751	10 Ophthalmic 眼科學	ISO	ISO 9394	2012	Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of biocompatibility by ocular study with rabbit eyes	原採認標準
752	10 Ophthalmic 眼科學	ANSI	ANSI Z80.7	2018	Ophthalmic Optics – Intraocular Lenses	原採認標準
753	10 Ophthalmic 眼科學	ISO	ISO 18189	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
754	10 Ophthalmic 眼科學	ANSI	ANSI Z80.36	2021	Ophthalmic – Light Hazard Protection for Ophthalmic Instruments	原採認標準
755	10 Ophthalmic 眼科學	ISO	ISO 11979-2	2014	Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods - Second Edition	原採認標準
756	10 Ophthalmic 眼科學	ISO	ISO 14730	2014	Ophthalmic optics -- Contact lens care products -- Antimicrobial preservative efficacy testing and guidance on determining discard date	原採認標準
757	10 Ophthalmic 眼科學	IEC	IEC 80601-2-58	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
758	10 Ophthalmic 眼科學	ISO	ISO 10936-1	2017	Optics and photonics - Operation microscopes - Part 1: Requirements and test methods	原採認標準
759	10 Ophthalmic 眼	ISO	ISO 11979-10	2018	Ophthalmic implants - Intraocular lenses - Part 10: Clinical	原採認標準

	科學				investigations of intraocular lenses for correction of ametropia in phakic eyes	
760	10 Ophthalmic 眼科學	ISO	ISO 11979-8	2017	Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements	原採認標準
761	10 Ophthalmic 眼科學	ISO	ISO 11981	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
762	10 Ophthalmic 眼科學	ISO	ISO 11986	2017	Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release	原採認標準
763	10 Ophthalmic 眼科學	ISO	ISO 15798	2017	Ophthalmic implants—Ophthalmic viscosurgical devices—Amendment 1	原採認標準
764	10 Ophthalmic 眼科學	ISO	ISO 18369-1	2017	Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications	原採認標準
765	10 Ophthalmic 眼科學	ISO	ISO 18369-2	2017	Ophthalmic optics - Contact lenses - Part 2: Tolerances	原採認標準
766	10 Ophthalmic 眼科學	ISO	ISO 18369-3	2017	Ophthalmic optics - Contact lenses - Part 3: Measurement methods	原採認標準
767	10 Ophthalmic 眼科學	ISO	ISO 18369-4	2017	Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials	原採認標準
768	10 Ophthalmic 眼科學	ISO	ISO 8980-1	2017	Ophthalmic optics - Uncut finished spectacle lenses - Part 1: Specifications for single-vision and multifocal lenses	原採認標準
769	10 Ophthalmic 眼科學	ISO	ISO 8980-2	2017	Ophthalmic optics - Uncut finished spectacle lenses - Part 2: Specifications for power-variation lenses	原採認標準

770	10 Ophthalmic 眼科學	ISO	ISO 11979-7	2018	Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia	原採認標準
771	10 Ophthalmic 眼科學	ISO	ISO 11979-1	2018	Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary - Third Edition	原採認標準
772	10 Ophthalmic 眼科學	ASTM	ASTM D882	2018	Standard Test Method for Tensile Properties of Thin Plastic Sheeting	原採認標準
773	10 Ophthalmic 眼科學	ISO	ISO 15004-2	2007	Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection	原採認標準
774	10 Ophthalmic 眼科學	ISO	ISO 16971	2015	Ophthalmic instruments — Optical coherence tomograph for the posterior segment of the human eye	原採認標準
775	10 Ophthalmic 眼科學	ISO	ISO 15004-1	2020	Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments	原採認標準
776	10 Ophthalmic 眼科學	ANSI	ANSI Z80.20	2016	Contact Lenses - Standard Terminology, Tolerances Measurements and Physiochemical Properties	原採認標準
777	10 Ophthalmic 眼科學	ISO	ISO 16672	2020	Ophthalmic implants - Ocular endotamponades	原採認標準
778	10 Ophthalmic 眼科學	ISO	ISO TR 22979	2017	Ophthalmic implants - Intraocular Lenses - Guidance on assessment of the need for clinical investigation of intraocular lens design modifications	原採認標準
779	10 Ophthalmic 眼科學	ISO	11979-10 Second edition 2018-03	2018	Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes.	113 年度新增採認標準
780	10 Ophthalmic 眼	ISO	10942 Third	2022	Ophthalmic instruments - Direct ophthalmoscopes	113 年度新增採

	科學		edition 2022-01			認標準
781	11 Orthopaedics 骨科學	ISO	ISO 5838-2	1991	Implants for surgery -- Skeletal pins and wires -- Part 2: Steinmann skeletal pins -- Dimensions	原採認標準
782	11 Orthopaedics 骨科學	ISO	ISO 5838-3	1993	Implants for surgery -- Skeletal pins and wires -- Part 3: Kirschner skeletal wires	原採認標準
783	11 Orthopaedics 骨科學	ISO	ISO 7207-1	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
784	11 Orthopaedics 骨科學	ISO	ISO 14243-1	2020	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 — Amendment 1	原採認標準
785	11 Orthopaedics 骨科學	ISO	ISO 14602	2010	Non-active surgical implants -- Implants for osteosynthesis -- Particular requirements	原採認標準
786	11 Orthopaedics 骨科學	ISO	ISO 14630	2012	Non-active surgical implants -- General requirements	原採認標準
787	11 Orthopaedics 骨科學	ISO	ISO 5833	2002	Implants for Surgery - Acrylic Resin Cements - Second Edition	原採認標準
788	11 Orthopaedics 骨科學	ISO	ISO 5838-1	2013	Implants for surgery -- Metallic skeletal pins and wires -- Part 1: General requirements	原採認標準
789	11 Orthopaedics 骨科學	ASTM	ASTM F1820	2013	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices	原採認標準
790	11 Orthopaedics 骨科學	ASTM	ASTM F2665	2021	Standard Specification for Total Ankle Replacement Prosthesis	原採認標準

791	11 Orthopaedics 骨科學	ASTM	ASTM F2996	2020	Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems	原採認標準
792	11 Orthopaedics 骨科學	ASTM	ASTM D2990	2017	Standard Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics	原採認標準
793	11 Orthopaedics 骨科學	ASTM	ASTM D790	2017	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	原採認標準
794	11 Orthopaedics 骨科學	ASTM	ASTM F116	2021	Standard Specification for Medical Screwdriver Bits	原採認標準
795	11 Orthopaedics 骨科學	ASTM	ASTM F2091	2015	Standard Specification for Acetabular Prostheses	原採認標準
796	11 Orthopaedics 骨科學	ASTM	ASTM F2180	2017	Standard Specification for Metallic Implantable Strands and Cables	原採認標準
797	11 Orthopaedics 骨科學	ASTM	ASTM F2582	2020	Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components	原採認標準
798	11 Orthopaedics 骨科學	ASTM	ASTM F2887	2017	Standard Specification for Total Elbow Prostheses	原採認標準
799	11 Orthopaedics 骨科學	ASTM	ASTM F2979	2020	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
800	11 Orthopaedics 骨科學	ASTM	ASTM F3161	2016	Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions	原採認標準
801	11 Orthopaedics 骨科學	ASTM	ASTM F451	2021	Standard Specification for Acrylic Bone Cement	原採認標準

802	11 Orthopaedics 骨科學	ISO	ISO 14242-2	2016	Implants for surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement	原採認標準
803	11 Orthopaedics 骨科學	ISO	ISO 14243-2	2016	Implants for surgery - Wear of total knee-joint prostheses - Part 2: Methods of measurement	原採認標準
804	11 Orthopaedics 骨科學	ISO	ISO 21535	2016	Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants	原採認標準
805	11 Orthopaedics 骨科學	ISO	ISO 21536	2014	Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants - Amendment 1	原採認標準
806	11 Orthopaedics 骨科學	ISO	ISO 7207-2	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
807	11 Orthopaedics 骨科學	ASTM	ASTM D732	2017	Standard Test Method for Shear Strength of Plastics by Punch Tool	原採認標準
808	11 Orthopaedics 骨科學	ASTM	ASTM F1541	2017	Standard Specification and Test Methods for External Skeletal Fixation Devices	原採認標準
809	11 Orthopaedics 骨科學	ASTM	ASTM F1829	2017	Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear	原採認標準
810	11 Orthopaedics 骨科學	ASTM	ASTM F1978	2018	Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser	原採認標準
811	11 Orthopaedics 骨科學	ASTM	ASTM F2028	2017	Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation	原採認標準
812	11 Orthopaedics 骨科學	ASTM	ASTM F2502	2017	Test Methods For Intervertebral Body Fusion Devices	原採認標準

813	11 Orthopaedics 骨科學	ISO	ISO 13175-3	2012	Implants for surgery - Calcium phosphates - Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes	原採認標準
814	11 Orthopaedics 骨科學	ASTM	ASTM F2267	2018	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression	原採認標準
815	11 Orthopaedics 骨科學	ASTM	ASTM F1714	2018	Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices.	原採認標準
816	11 Orthopaedics 骨科學	ASTM	ASTM F2423	2020	Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses	原採認標準
817	11 Orthopaedics 骨科學	ASTM	ASTM F2624	2020	Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs	原採認標準
818	11 Orthopaedics 骨科學	ASTM	ASTM F1378	2018	Standard Specification for Shoulder Prostheses	原採認標準
819	11 Orthopaedics 骨科學	ASTM	ASTM F1717	2018	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	原採認標準
820	11 Orthopaedics 骨科學	ASTM	ASTM F2077	2018	Test Methods For Intervertebral Body Fusion Devices	原採認標準
821	11 Orthopaedics 骨科學	ASTM	ASTM F2554	2018	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems	原採認標準
822	11 Orthopaedics 骨科學	ISO	ISO 14242-3	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	原採認標準
823	11 Orthopaedics 骨	ASTM	ASTM F2580	2018	Standard Practice for Evaluation of Modular Connection of	原採認標準

	科學				Proximally Fixed Femoral Hip Prosthesis	
824	11 Orthopaedics 骨科學	ASTM	ASTM F2193	2020	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	原採認標準
825	11 Orthopaedics 骨科學	ISO	ISO 14242-1	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	原採認標準
826	11 Orthopaedics 骨科學	ISO	ISO 19227	2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements - First Edition	原採認標準
827	11 Orthopaedics 骨科學	ASTM	ASTM F2789	2020	Standard Guide for Mechanical and Functional Characterization of Nucleus Devices	原採認標準
828	11 Orthopaedics 骨科學	ASTM	ASTM F2009	2020	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses	原採認標準
829	11 Orthopaedics 骨科學	ASTM	ASTM F2381	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	原採認標準
830	11 Orthopaedics 骨科學	ASTM	ASTM F2943	2019	Standard Guide for Presentation of End User Labeling Information for Orthopedic Implants Used in Joint Arthroplasty.	原採認標準
831	11 Orthopaedics 骨科學	ASTM	ASTM F1357	2019	Standard Specification for Articulating Total Wrist Implants	原採認標準
832	11 Orthopaedics 骨科學	ASTM	ASTM F1611	2020	Standard Specification for Intramedullary Reamers	原採認標準
833	11 Orthopaedics 骨科學	ASTM	ASTM F2385	2019	Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs	原採認標準

834	11 Orthopaedics 骨科學	ISO	ISO 14243-3	2020	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	原採認標準
835	11 Orthopaedics 骨科學	ASTM	ASTM E399	2020	Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Metallic Materials	原採認標準
836	11 Orthopaedics 骨科學	ISO	ISO 15142-2	2003	Implants for surgery - Metal intramedullary nailing systems - Part 2: Locking components	原採認標準
837	11 Orthopaedics 骨科學	ISO	ISO 15142-1	2003	Implants for surgery — Metal intramedullary nailing systems — Part 1: Intramedullary nails	原採認標準
838	11 Orthopaedics 骨科學	ASTM	ASTM F1264	2016	Standard Specification and Test Methods for Intramedullary Fixation Devices	原採認標準
839	11 Orthopaedics 骨科學	ASTM	ASTM F543	2017	Standard Specification and Test Methods for Metallic Medical Bone Screws	原採認標準
840	11 Orthopaedics 骨科學	ASTM	F897	2019	Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	原採認標準
841	11 Orthopaedics 骨科學	ASTM	F1800	2019	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	原採認標準
842	11 Orthopaedics 骨科學	ASTM	F3334	2019	Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components	原採認標準
843	11 Orthopaedics 骨科學	ASTM	F3292	2019	Standard Practice for Inspection of Spinal Implants Undergoing Testing	原採認標準
844	11 Orthopaedics 骨科學	ASTM	ASTM F382	2017	Standard Specification and Test Method for Metallic Bone Plates	原採認標準

845	11 Orthopaedics 骨科學	ASTM	ASTM F564	2017	Standard specification and test methods for metallic bone staples	原採認標準
846	11 Orthopaedics 骨科學	ASTM	ASTM F3143	2020	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings under Standard Conditions Using a Reciprocal Friction Simulator	原採認標準
847	11 Orthopaedics 骨科學	ASTM	ASTM F3446	2020	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator	原採認標準
848	11 Orthopaedics 骨科學	ASTM	ASTM F1223	2020	Standard Test Method for Determination of Total Knee Replacement Constraint	原採認標準
849	11 Orthopaedics 骨科學	ISO	ISO 14879-1	2020	Implants for surgery - Total knee-joint prostheses - Part 1: Determination of endurance properties of knee tibial trays	原採認標準
850	11 Orthopaedics 骨科學	ASTM	ASTM F3090	2020	Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement	原採認標準
851	11 Orthopaedics 骨科學	ASTM	ASTM F2033	2020	Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic Ceramic and Polymeric Materials	原採認標準
852	11 Orthopaedics 骨科學	ASTM	ASTM F2723	2021	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation	原採認標準
853	11 Orthopaedics 骨科學	ASTM	F1820-22	2022	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices	113 年度新增採認標準
854	11 Orthopaedics 骨科學	ASTM	F1357 - 23	2023	Standard Specification for Articulating Total Wrist Implants	113 年度新增採認標準
855	11 Orthopaedics 骨	ASTM	F3210-22e1	2022	Standard Test Method for Fatigue Testing of Total Knee Femoral	113 年度新增採

	科學				Components Under Closing Conditions	認標準
856	11 Orthopaedics 骨科學	ASTM	F3574-22	2022	Standard Test Methods for Sacroiliac Joint Fusion Devices	113 年度新增採認標準
857	11 Orthopaedics 骨科學	ASTM	F1814-22	2022	Standard Guide for Evaluating Modular Hip and Knee Joint Components	113 年度新增採認標準
858	11 Orthopaedics 骨科學	ISO	7206-13 First edition 2016-07-01 [Including AMD1:2022]	2016	Implants for surgery - Partial and total hip joint prostheses - Part 13: Determination of resistance to torque of head fixation of stemmed femoral components [Including AMENDMENT 1 (2022)]	113 年度新增採認標準
859	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-7	1998	Wheelchairs -- Part 7: Measurement of seating and wheel dimensions	原採認標準
860	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-13	1989	Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces	原採認標準
861	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-15	1996	Wheelchairs - Part 15: Requirements for Information Disclosure, Documentation and Labelling	原採認標準
862	12 Physical Medicine 物理醫學科學	CNS	CNS 15037-1	2006	雙臂操作步行輔具－要求及測試法－第 1 部：助行器	原採認標準
863	12 Physical Medicine 物理醫	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

	學科學					
864	12 Physical Medicine 物理醫學科學	CNS	CNS 15037-3	2006	雙臂操作步行輔具－要求及測試法－第 3 部：附前臂支撐桌助行器	原採認標準
865	12 Physical Medicine 物理醫學科學	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
866	12 Physical Medicine 物理醫學科學	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
867	12 Physical Medicine 物理醫學科學	CNS	CNS 14103-2	2009	義肢學與矯具學－詞彙－第 2 部：外用義肢與其穿戴者之術語	原採認標準
868	12 Physical Medicine 物理醫學科學	CNS	CNS 14103-3	2009	義肢學與矯具學－詞彙－第 3 部：外用矯具之術語	原採認標準
869	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-1	2009	義肢學與矯具學－肢體缺陷－第 1 部：先天性肢體缺陷之描述	原採認標準
870	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-2	2009	義肢學與矯具學－肢體缺陷－第 2 部：下肢截肢之描述	原採認標準
871	12 Physical Medicine 物理醫	CNS	CNS 14104-3	2009	義肢學與矯具學－肢體缺陷－第 3 部：上肢截肢之描述	原採認標準

	學科學					
872	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-4	2009	義肢學與矯具學－肢體缺陷－第 4 部：導致截肢原因之描述	原採認標準
873	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-5	2009	義肢學與矯具學－肢體缺陷－第 5 部：截肢病患臨床狀態之描述	原採認標準
874	12 Physical Medicine 物理醫學科學	CNS	CNS 15265-1	2009	義肢學與矯具學－義肢組件之分類與描述－第 1 部：義肢組件之分類	原採認標準
875	12 Physical Medicine 物理醫學科學	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
876	12 Physical Medicine 物理醫學科學	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
877	12 Physical Medicine 物理醫學科學	CNS	CNS 15266	2009	義肢學—髖關節結構之測試方法	原採認標準
878	12 Physical Medicine 物理醫學科學	CNS	CNS 15268	2009	外用義肢與外用矯具－要求與測試方法	原採認標準
879	12 Physical Medicine 物理醫	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

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880	12 Physical Medicine 物理醫學科學	CNS	CNS 14964	2007	輪椅－應用指導綱要	原採認標準
881	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-1	2017	輪椅－第 1 部：靜態穩定性之測定	原採認標準
882	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-2	2007	輪椅－第 2 部：電動輪椅動態穩定性之測定	原採認標準
883	12 Physical Medicine 物理醫學科學	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
884	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-6	2005	輪椅－第 6 部：電動輪椅最大速率之測定	原採認標準
885	12 Physical Medicine 物理醫學科學	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
886	12 Physical Medicine 物理醫學科學	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
887	12 Physical Medicine 物理醫	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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888	12 Physical Medicine 物理醫學科學	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
889	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-14	2005	輪椅－第 14 部：電動輪椅之電力與控制系統測試方法與要求	原採認標準
890	12 Physical Medicine 物理醫學科學	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
891	12 Physical Medicine 物理醫學科學	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
892	12 Physical Medicine 物理醫學科學	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
893	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-22	2022	輪椅－第 22 部：設定程序	原採認標準
894	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-4	2008	Wheelchairs -- Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	原採認標準
895	12 Physical Medicine 物理醫	ISO	ISO 7176-5	2008	Wheelchairs -- Part 5: Determination of dimensions, mass and manoeuvring space	原採認標準

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896	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-9	2009	Wheelchairs -- Part 9: Climatic tests for electric wheelchairs	原採認標準
897	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-10	2008	Wheelchairs -- Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	原採認標準
898	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-14	2008	Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods	原採認標準
899	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-21	2009	Wheelchairs -- Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	原採認標準
900	12 Physical Medicine 物理醫學科學	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
901	12 Physical Medicine 物理醫學科學	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
902	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-11	2012	Wheelchairs -- Part 11: Test dummies	原採認標準
903	12 Physical	ISO	ISO 16840-10	2021	Wheelchair seating — Part 10: Resistance to ignition of postural	原採認標準

	Medicine 物理醫學科學				support devices — Requirements and test method	
904	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-3	2012	Wheelchairs -- Part 3: Determination of effectiveness of brakes	原採認標準
905	12 Physical Medicine 物理醫學科學	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
906	12 Physical Medicine 物理醫學科學	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
907	12 Physical Medicine 物理醫學科學	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
908	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-3	2015	輪椅－第 3 部：煞車有效性之測定	原採認標準
909	12 Physical Medicine 物理醫學科學	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
910	12 Physical Medicine 物理醫	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

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911	12 Physical Medicine 物理醫學科學	CNS	CNS 15191	2012	木手杖	原採認標準
912	12 Physical Medicine 物理醫學科學	CNS	CNS 15192	2013	非木質手杖	原採認標準
913	12 Physical Medicine 物理醫學科學	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
914	12 Physical Medicine 物理醫學科學	CNS	CNS 15910-1	2016	家用之褥瘡防止鋪墊－第 1 部：種類	原採認標準
915	12 Physical Medicine 物理醫學科學	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
916	12 Physical Medicine 物理醫學科學	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
917	12 Physical Medicine 物理醫學科學	EN	EN 12183	2014	Manual wheelchairs - Requirements and test methods	原採認標準
918	12 Physical Medicine 物理醫	EN	EN 12184	2014	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods	原採認標準

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919	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-1	2014	Wheelchairs - Part 1: Determination of Static Stability	原採認標準
920	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-22	2014	Wheelchairs -- Part 22: Set-up procedures	原採認標準
921	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-8	2014	Wheelchairs -- Part 8: Requirements and test methods for static, impact and fatigue strengths	原採認標準
922	12 Physical Medicine 物理醫學科學	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
923	12 Physical Medicine 物理醫學科學	CNS	CNS 16010-2	2017	尿液吸收輔具－詞彙－第 2 部：產品	原採認標準
924	12 Physical Medicine 物理醫學科學	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
925	12 Physical Medicine 物理醫學科學	IEC	IEC 60601-2-3	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
926	12 Physical Medicine 物理醫	IEC	IEC 60601-2-6	2016	Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave	原採認標準

	學科學				therapy equipment	
927	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-19	2015	Wheelchairs Part 19: Wheeled mobility devices for use as seats in motor vehicles	原採認標準
928	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-2	2017	Wheelchairs - Part 2: Determination of Dynamic Stability of Electric Wheelchairs	原採認標準
929	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-6	2018	Wheelchairs - Part 6:Determination of maximum speed, acceleration and deceleration of electric wheelchairs	原採認標準
930	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-28	2012	Wheelchairs - Part 28: Requirements and test methods for stair-climbing devices	原採認標準
931	12 Physical Medicine 物理醫學科學	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
932	12 Physical Medicine 物理醫學科學	ISO	ISO 11199-2	2021	Assistive products for walking manipulated by both arms — Requirements and test methods — Part 2: Rollators	原採認標準
933	12 Physical Medicine 物理醫學科學	CNS	CNS 16051	2018	具電動輔助起站及坐下機構之座椅與椅座	原採認標準
934	12 Physical Medicine 物理醫	CNS	CNS 16077	2018	身心障礙者移位用起吊裝置－要求及試驗法	原採認標準

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935	12 Physical Medicine 物理醫學科學	Japanese Standards Association	JIS D9301	2013	Bicycles For General Use	原採認標準
936	12 Physical Medicine 物理醫學科學	IEC	IEC 80601-2-78	2019	Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation	原採認標準
937	12 Physical Medicine 物理醫學科學	Cenelec	EN IEC 60601-2-83	2021	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	原採認標準
938	12 Physical Medicine 物理醫學科學	ISO	16840-10 Second edition 2021-06 Corrected version 2022-01	2021	Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method	113 年度新增採認標準
939	12 Physical Medicine 物理醫學科學	ISO	7176-14 Third Edition 2022	2022	Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods	113 年度新增採認標準
940	12 Physical Medicine 物理醫學科學	ISO	7176-25 Second Edition 2022	2022	Wheelchairs - Part 25: Lead-acid batteries and chargers for powered wheelchairs - Requirements and test methods	113 年度新增採認標準

941	12 Physical Medicine 物理醫學科學	ISO	7176-19 Third Edition 2022	2022	Wheelchairs - Part 19: Wheeled mobility devices for use as seats in motor vehicles	113 年度新增採認標準
942	12 Physical Medicine 物理醫學科學	ISO	ISO 11199-3:2005		Walking aids manipulated by both arms — Requirements and test methods — Part 3: Walking tables	113 年度新增採認標準
943	12 Physical Medicine 物理醫學科學	ISO	ISO 11199-1:2021	2021	Assistive products for walking manipulated by both arms — Requirements and test methods — Part 1: Walking frames	113 年度新增採認標準
944	12 Physical Medicine 物理醫學科學	ISO	ISO 22523	2006	External limb prostheses and external orthoses — Requirements and test methods	113 年度新增採認標準
945	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO2-A2	2006	Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition	原採認標準
946	13 Software/Informatics 軟體/醫療資訊	IEC	ISO/IEC 25062	2006	Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability test reports	原採認標準
947	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO8-A	2006	Managing and Validating Laboratory Information Systems; Approved Guideline	原採認標準
948	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO10-A	2006	Autoverification of Clinical Laboratory Test Results	原採認標準

949	13 Software/Informatics 軟體/醫療資訊	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
950	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 80002-1	2009	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software	原採認標準
951	13 Software/Informatics 軟體/醫療資訊	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
952	13 Software/Informatics 軟體/醫療資訊	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
953	13 Software/Informatics 軟體/醫療資訊	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
954	13 Software/Informatics 軟體/醫療資訊	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
955	13 Software/Informatics 軟體/醫療資訊	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
956	13 Software/Informatics 軟體/醫療資訊	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

957	13 Software/Informatics 軟體/醫療資訊	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
958	13 Software/Informatics 軟體/醫療資訊	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
959	13 Software/Informatics 軟體/醫療資訊	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
960	13 Software/Informatics 軟體/醫療資訊	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
961	13 Software/Informatics 軟體/醫療資訊	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
962	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-14	2010	健康資訊交換第七層協定－第 14 部：應用管理	原採認標準
963	13 Software/Informatics 軟體/醫療資訊	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
964	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-1	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

965	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-2	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
966	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-3	2012	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks	原採認標準
967	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-4	2012	Application of risk management for IT-networks incorporating medical devices ─ Part 2-4: General implementation guidance for healthcare delivery organizations	原採認標準
968	13 Software/Informatics 軟體/醫療資訊	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
969	13 Software/Informatics 軟體/醫療資訊	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
970	13 Software/Informatics 軟體/醫療資訊	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
971	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 62443-2-1	2010	Industrial communication networks—Network and system security—Part 2–1: Establishing an industrial automation and control system security program.	原採認標準
972	13 Software/Informatics	IEC	IEC 80001-1	2010	Application of risk management for IT Networks incorporating medical devices — Part 1: Roles, responsibilities and activities	原採認標準

	軟體/醫療資訊					
973	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 80002-1	2009	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software - Edition 1.0	原採認標準
974	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 62443-3-1	2009	Industrial communication networks—Network and system security—Part 3–1: Security technologies for industrial automation and control systems.	原採認標準
975	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TS 62443-1-1	2009	Industrial communication networks—Network and system security—Part 1–1: Terminology,concepts and models	原採認標準
976	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEC/IEEE 15026-4	2021	Systems and software engineering — Systems and software assurance — Part 4: Assurance in the life cycle	原採認標準
977	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEC 25001	2014	Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Planning and management - Second Edition	原採認標準
978	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEC 25051	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
979	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10404	2010	Health informatics Personal health device communication Part 10404: Device specialization Pulse oximeter	原採認標準
980	13	ISO	ISO/IEEE	2012	Health informatics--Personal health device communication Part	原採認標準

	Software/Informatics 軟體/醫療資訊		11073-10406		10406: Device specialization--Basic electrocardiograph (ECG) (1- to 3-lead ECG)	
981	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10407	2010	ISO/IEEE Health informatics Personal health device communication Part 10407: Device specialization Blood pressure monitor	原採認標準
982	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10408	2010	Health Informatics-Personal Health Device Communication Part 10408: Device Specialization-Thermometer	原採認標準
983	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10415	2010	Health Informatics-Personal Health Device Communication Part 10415: Device Specialization-Weighing Scale	原採認標準
984	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10472	2012	Health Informatics—Personal health device communication—Part 10472 Device specialization—Medication monitor	原採認標準
985	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-20101	2004	IEEE Standard for Health Informatics - Point-Of-Care Medical Device Communication - Part 20101: Application Profile - Base Standard	原採認標準
986	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 62304	2015	Medical device software - Software life cycle processes	原採認標準
987	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 82304-1	2016	Health software - Part 1: General requirements for product safety - Edition 1.0	原採認標準
988	13	IEC	IEC/TR	2014	Application of risk management for IT-networks incorporating	原採認標準

	Software/Informatics 軟體/醫療資訊		80001-2-5		medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems - Edition 1.0	
989	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 80002-3	2014	Medical device software –Part 3: Process reference model of medical device software life cycle processes (IEC 62304)	原採認標準
990	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10417	2015	Health Informatics-Personal health device communication Part 10417: Device specialization-Glucose meter	原採認標準
991	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10422	2016	Health informatics-Personal health device communication Part 10422: Device specialization - Urine analyzer	原採認標準
992	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10424	2017	Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE)	原採認標準
993	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 3333.2.1	2015	IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling	原採認標準
994	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/TR 80001-2-6	2014	Application of risk management for IT-networks incorporating medical devices — Part 2-6: Application guidance — Guidance for responsibility agreements	原採認標準
995	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/TR 80002-2	2017	Medical device software - Part 2: Validation of software for medical device quality systems	原採認標準
996	13	ISO	ISO/IEEE	2012	Health informatics—Personal health device communication Part	原採認標準

	Software/Informatics 軟體/醫療資訊		11073-10421		10421: Device specialization—Peak expiratory flow monitor (peak flow)	
997	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 1012	2017	IEEE Standard for System and Software Verification and Validation	原採認標準
998	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 11073-10425	2017	Health informatics—Personal health device communication Part 10425: Device Specialization—Continuous Glucose Monitor (CGM)	原採認標準
999	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 11073-20601	2016	Health informatics--Personal health device communication Part 20601: Application profile-Optimized Exchange Protocol.	原採認標準
1000	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE/IEC/ISO 12207	2017	Systems and software engineering -- Software life cycle processes	原採認標準
1001	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10102	2014	Health informatics -- Point-of-care medical device communication Part 10102: Nomenclature --Annotated ECG	原採認標準
1002	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10417	2017	IEEE Health informatics -- Personal health device communication Part 10417: Device Specialization -- Glucose Meter	原採認標準
1003	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR45	2018	Guidance on the use of AGILE practices in the development of medical device software	原採認標準
1004	13	ASTM	ASTM F2761	2013	Medical Devices and Medical Systems - Essential safety	原採認標準

	Software/Informatics 軟體/醫療資訊				requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model	
1005	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10418	2016	Health informatics—Personal health device communication—Part 10418 Device specialization—International normalized ratio (INR) monitor	原採認標準
1006	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10101	2020	Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature	原採認標準
1007	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10207	2017	Health informatics—Point-of-care medical device communication Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication.	原採認標準
1008	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-20702	2018	Health informatics—Point-of-care medical device communication—Part 20702: Medical devices communication profile for web services	原採認標準
1009	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10201	2020	ISO/IEEE Health Informatics - Point-Of-Care Medical Device Communication - Part 10201: Domain Information Model	原採認標準
1010	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR57	2019	Principles for medical device security—Risk management	原採認標準
1011	13 Software/Informatics	ISO/IEC	ISO/IEC 27035-1	2016	Information technology — Security techniques — Information security incident management — Part 1: Principles of incident	原採認標準

	軟體/醫療資訊				management	
1012	13 Software/Informatics 軟體/醫療資訊	ISO/IEC	ISO/IEC 27035-2	2016	Information technology — Security techniques — Information security incident management — Part 2: Guidelines to plan and prepare for incident response	原採認標準
1013	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR 97	2019	Principles for medical device security—Postmarket risk management for device manufacturers	原採認標準
1014	13 Software/Informatics 軟體/醫療資訊	ISO/IEC	ISO/IEC 27000	2018	Information security management systems	原採認標準
1015	13 Software/Informatics 軟體/醫療資訊	IEC	IEC TR 80001-2-8	2016	Application of risk management for IT-networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2	原採認標準
1016	13 Software/Informatics 軟體/醫療資訊	ANSI UL	ANSI UL 2900-1	2017	Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements	原採認標準
1017	13 Software/Informatics 軟體/醫療資訊	ANSI UL	ANSI UL 2900-2-1	2017	Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems	原採認標準
1018	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-40102	2020	Health informatics - Device interoperability. Part 40102: Foundational - Cybersecurity - Capabilities for mitigation.	原採認標準
1019	13	IEEE	IEEE Std	2020	Health informatics - Device interoperability Part 40101:	原採認標準

	Software/Informatics 軟體/醫療資訊		11073-40101		Foundational - Cybersecurity - Processes for vulnerability assessment.	
1020	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI	ANSI AAMI 2700-1	2019	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	原採認標準
1021	13 Software/Informatics 軟體/醫療資訊	IEEE UL	Std 2621.2-2022	2022	Standard for Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions	113 年度新增採認標準
1022	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	2800-1:2022	2022	Standard for Medical Device Interoperability	113 年度新增採認標準
1023	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	2800-1-2:2022	2022	Standard for Interoperable Item Development Life Cycle	113 年度新增採認標準
1024	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	2800-1-3:2022	2022	Standard for Interoperable Item Integration Life Cycle	113 年度新增採認標準
1025	13 Software/Informatics 軟體/醫療資訊	IEC	81001-5-1 Edition 1.0 2021-12	2021	Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle	113 年度新增採認標準
1026	13 Software/Informatics 軟體/醫療資訊	ANSI NEMA	HN 1-2019	2019	American National Standard Manufacturer Disclosure Statement for Medical Device Security	113 年度新增採認標準

1027	13 Software/Informatics 軟體/醫療資訊	AAMI	CR34971:2022	2022	Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning	113 年度新增採認標準
1028	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	2800-1-1:2022	2022	Standard for Risk Concerns for Interoperable Medical Products	113 年度新增採認標準
1029	14 Radiology 放射學科學	ISO	ISO 12005	2003	Lasers and laser-related equipment - Test methods for laser beam parameters - Polarization	原採認標準
1030	14 Radiology 放射學科學	ISO	ISO 13696	2002	Optics and optical instruments -- Test methods for radiation scattered by optical components	原採認標準版本更新
1031	14 Radiology 放射學科學	IEC	IEC 61847	1998	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics Ed. 1.0	原採認標準
1032	14 Radiology 放射學科學	ISO	ISO 11146-2	2021	Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 2: General astigmatic beams	原採認標準
1033	14 Radiology 放射學科學	ISO	ISO/TR 11146-3	2005	Lasers and laser-related equipment -- Test methods for laser beam widths, divergence angles and beam propagation ratios -- Part 3: Intrinsic and geometrical laser beam classification, propagation and details of test methods	原採認標準
1034	14 Radiology 放射學科學	ISO	ISO 9236-1	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
1035	14 Radiology 放射學科學	ISO	ISO 4090	2001	Photography - Medical radiographic cassette/screens/films and hard-copy imaging films - Dimensions and specifications	原採認標準

1036	14 Radiology 放射學科學	ISO	ISO 5799	1991	Photography -- Direct-exposing medical and dental radiographic film/process systems -- Determination of ISO speed and ISO average gradient	原採認標準
1037	14 Radiology 放射學科學	ISO	ISO 15367-1	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
1038	14 Radiology 放射學科學	ISO	ISO 15367-2	2005	Lasers and laser-related equipment - Test methods for determination of the shape of a laser beam wavefront - Part 2: Shack-Hartman sensors	原採認標準
1039	14 Radiology 放射學科學	IEC	IEC/TR 60825-14	2004	Safety of laser products - Part 14: A user's guide	原採認標準
1040	14 Radiology 放射學科學	IEC	IEC/TR 60825-8	2006	Safety of laser products - Part 8: Guidelines for the safe use of laser beams on humans	原採認標準
1041	14 Radiology 放射學科學	IEC	IEC 60601-2-29	2008	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	原採認標準
1042	14 Radiology 放射學科學	ISO	ISO 11670	2004	Lasers and laser-related equipment -- Test methods for laser beam parameters -- Beam positional stability	原採認標準
1043	14 Radiology 放射學科學	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
1044	14 Radiology 放射學科學	IEC	IEC 60601-2-5	2009	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	原採認標準
1045	14 Radiology 放射	IEC	IEC/TR 60825-3	2008	Safety of laser products - Part 3: Guidance for laser	原採認標準

	學科學				displays and shows	
1046	14 Radiology 放射學科學	IEC	IEC 60976	2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	原採認標準
1047	14 Radiology 放射學科學	ISO	ISO 21254-3	2011	Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Part 3: Assurance of laser power (energy) handling capabilities - First Edition	原採認標準
1048	14 Radiology 放射學科學	ISO	ISO TR 21254-4	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
1049	14 Radiology 放射學科學	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
1050	14 Radiology 放射學科學	CNS	CNS 15586	2013	醫電設備電性安全－醫用診斷 X 射線管組件－焦斑特性 (Medical electrical equipment – X-ray tube assemblies for medical diagnosis –Characteristics of focal spots (IDT: IEC 60336:2005))	原採認標準
1051	14 Radiology 放射學科學	CNS	CNS 15587	2013	醫用診斷 X 射線設備－用於測定特性的輻射條件 (Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics (IDT: IEC 61267:2005))	原採認標準
1052	14 Radiology 放射學科學	IEC	IEC 60601-1-3	2021	Amendment 2 - Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard:	原採認標準

					Radiation protection in diagnostic X-ray equipment	
1053	14 Radiology 放射學科學	IEC	IEC 60601-2-11	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
1054	14 Radiology 放射學科學	IEC	IEC 60627	2013	Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids - Edition 3.0	原採認標準
1055	14 Radiology 放射學科學	IEC	IEC 60825-1	2017	Interpretation sheet 1 - Safety of laser products - Part 1: Equipment classification and requirements	原採認標準
1056	14 Radiology 放射學科學	IEC	IEC 60825-2	2021	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCSs)	原採認標準
1057	14 Radiology 放射學科學	IEC	IEC 60825-4	2011	Safety of laser products – Part 4: Laser guards - Edition 2.2	原採認標準
1058	14 Radiology 放射學科學	IEC	IEC 61161	2013	Ultrasonics—Power measurement—Radiation force balances and performance requirements.	原採認標準
1059	14 Radiology 放射學科學	IEC	IEC 61217	2011	Radiotherapy equipment – Coordinates, movements and scales - Edition 2.0	原採認標準
1060	14 Radiology 放射學科學	IEC	IEC 61223-3-2	2007	Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment - Edition 2.0	原採認標準
1061	14 Radiology 放射學科學	IEC	IEC 61223-3-4	2000	Evaluation and Routine Testing in Medical Imaging Departments - Part 3-4: Acceptance Tests - Imaging	原採認標準

					Performance of Dental X-Ray Equipment - Edition 1.0	
1062	14 Radiology 放射學科學	IEC	IEC 61331-1	2014	Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials - Edition 2.0	原採認標準
1063	14 Radiology 放射學科學	IEC	IEC 61331-2	2014	Protective devices against diagnostic medical X-radiation – Part 2: Translucent protective plates - Edition 2.0	原採認標準
1064	14 Radiology 放射學科學	IEC	IEC 61331-3	2014	Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields - Edition 2.0	原採認標準
1065	14 Radiology 放射學科學	IEC	IEC 61674	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
1066	14 Radiology 放射學科學	IEC	IEC 61689	2013	Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz - Edition 3.0	原採認標準
1067	14 Radiology 放射學科學	IEC	IEC 62083	2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	原採認標準
1068	14 Radiology 放射學科學	IEC	IEC 62127-1	2013	Ultrasonics—Hydrophones—Part 1: Measurement and characterization of medical ultrasonic fields up to 40 megahertz (MHz).	原採認標準
1069	14 Radiology 放射學科學	IEC	IEC 62127-3	2013	Ultrasonics—Hydrophones—Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz.	原採認標準

1070	14 Radiology 放射學科學	IEC	IEC 62555	2013	Ultrasonics—Power measurement—High intensity therapeutic ultrasound (HITU) transducers and systems	原採認標準
1071	14 Radiology 放射學科學	IEEE	IEEE N42.13	2004	Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides	原採認標準
1072	14 Radiology 放射學科學	ISO	ISO 11146-1	2021	Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams	原採認標準
1073	14 Radiology 放射學科學	ISO	ISO 21254-1	2011	Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 1: Definitions and general principles	原採認標準
1074	14 Radiology 放射學科學	ISO	ISO 21254-2	2011	Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 2: Threshold determination	原採認標準
1075	14 Radiology 放射學科學	ISO	ISO 2919	2012	Radiological protection -- Sealed radioactive sources -- General requirements and classification	原採認標準
1076	14 Radiology 放射學科學	ISO	ISO/ASTM 51275	2013	Practice for use of a radiochromic film dosimetry system	原採認標準
1077	14 Radiology 放射學科學	ISO	ISO/ASTM 51607	2013	Practice for use of an alanine-EPR dosimetry system	原採認標準
1078	14 Radiology 放射學科學	ASTM	ASTM F2978	2020	Standards Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance	原採認標準

					Imaging	
1079	14 Radiology 放射學科學	EN	EN 62220-1-1	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
1080	14 Radiology 放射學科學	EN	EN 62570	2015	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	原採認標準
1081	14 Radiology 放射學科學	IEC	IEC 60601-2-1	2020	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
1082	14 Radiology 放射學科學	IEC	IEC 60601-2-17	2013	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
1083	14 Radiology 放射學科學	IEC	IEC 60601-2-33	2016	Corrigendum 2 - Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	原採認標準
1084	14 Radiology 放射學科學	IEC	IEC 60601-2-36	2014	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

1085	14 Radiology 放射學科學	IEC	IEC 60601-2-37	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
1086	14 Radiology 放射學科學	IEC	IEC 60601-2-44	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
1087	14 Radiology 放射學科學	IEC	IEC 60601-2-45	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	原採認標準版本更新
1088	14 Radiology 放射學科學	IEC	IEC 60601-2-62	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
1089	14 Radiology 放射學科學	IEC	IEC 60601-2-64	2014	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
1090	14 Radiology 放射	IEC	IEC 60601-2-68	2014	Medical electrical equipment - Part 2-68: Particular	原採認標準

	學科學				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	
1091	14 Radiology 放射學科學	IEC	IEC 60601-2-8	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
1092	14 Radiology 放射學科學	IEC	IEC 60731	2016	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy - Edition 3.1; Consolidated Reprint	原採認標準
1093	14 Radiology 放射學科學	ISO	ISO 11810	2015	Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Primary ignition, penetration, flame spread and secondary ignition	原採認標準
1094	14 Radiology 放射學科學	ISO	ISO/ASTM 51707	2015	Guide for estimating uncertainties in dosimetry for radiation processing	原採認標準
1095	14 Radiology 放射學科學	IEC	IEC 60601-2-28	2017	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

1096	14 Radiology 放射學科學	IEC	IEC 60601-2-63	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
1097	14 Radiology 放射學科學	IEC	IEC 60601-2-65	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
1098	14 Radiology 放射學科學	ISO	ISO 11554	2017	Optics and photonics -- Lasers and laser-related equipment -- Test methods for laser beam power, energy and temporal characteristics	原採認標準
1099	14 Radiology 放射學科學	ISO	ISO 12052	2017	Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management	原採認標準
1100	14 Radiology 放射學科學	IEC	IEC 60601-2-54	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
1101	14 Radiology 放射學科學	ISO	ISO 11670	2004	Lasers and laser-related equipment - Test methods for laser beam parameters - Beam positional stability	原採認標準
1102	14 Radiology 放射學科學	ASTM	ASTM D7866	2014	Standard Specification for Radiation Attenuating Protective Gloves	原採認標準
1103	14 Radiology 放射學科學	IEC	IEC 61223-3-5	2019	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment	原採認標準

1104	14 Radiology 放射學科學	IEC	IEC 80601-2-26	2019	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph	原採認標準
1105	14 Radiology 放射學科學	ISO	ISO 11990	2018	Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes Part 2: Tracheal tube cuffs	原採認標準
1106	14 Radiology 放射學科學	ISO	ISO 11551	2019	Optics and optical instruments - Lasers and laser-related equipment - Test method for absorptance of optical laser components	原採認標準
1107	14 Radiology 放射學科學	NEMA	DICOM PS3.1	2021	Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview	原採認標準
1108	14 Radiology 放射學科學	NEMA	DICOM PS3.10	2021	Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for Media Interchange	原採認標準
1109	14 Radiology 放射學科學	NEMA	DICOM PS3.11	2021	Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles	原採認標準
1110	14 Radiology 放射學科學	NEMA	DICOM PS3.12	2021	Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange	原採認標準
1111	14 Radiology 放射學科學	NEMA	DICOM PS3.14	2021	Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function	原採認標準
1112	14 Radiology 放射	NEMA	DICOM PS3.15	2021	Digital Imaging and Communications in Medicine	原採認標準

	學科學				(DICOM) Part 15: Security and System Management Profiles	
1113	14 Radiology 放射學科學	NEMA	DICOM PS3.16	2021	Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource	原採認標準
1114	14 Radiology 放射學科學	NEMA	DICOM PS3.17	2021	Digital Imaging and Communications in Medicine (DICOM) Part 17: Explanatory Information	原採認標準
1115	14 Radiology 放射學科學	NEMA	DICOM PS3.18	2021	Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Access to DICOM Persistent Objects (WADO)	原採認標準
1116	14 Radiology 放射學科學	NEMA	DICOM PS3.19	2021	Digital Imaging and Communications in Medicine (DICOM) Part 19: Application Hosting	原採認標準
1117	14 Radiology 放射學科學	NEMA	DICOM PS3.2	2021	Digital Imaging and Communications in Medicine (DICOM) Part 2: Conformance	原採認標準
1118	14 Radiology 放射學科學	NEMA	DICOM PS3.20	2021	Digital Imaging and Communications in Medicine (DICOM) Part 20: Transformation of DICOM to and from HL7 Standards	原採認標準
1119	14 Radiology 放射學科學	NEMA	DICOM PS3.3	2021	Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions	原採認標準
1120	14 Radiology 放射學科學	NEMA	DICOM PS3.4	2021	Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications	原採認標準
1121	14 Radiology 放射學科學	NEMA	DICOM PS3.5	2021	Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding	原採認標準
1122	14 Radiology 放射學科學	NEMA	DICOM PS3.6	2021	Digital Imaging and Communications in Medicine (DICOM) Part 6: Data Dictionary	原採認標準

1123	14 Radiology 放射學科學	NEMA	DICOM PS3.7	2021	Digital Imaging and Communications in Medicine (DICOM) Part 7: Message Exchange	原採認標準
1124	14 Radiology 放射學科學	NEMA	DICOM PS3.8	2021	Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange	原採認標準
1125	14 Radiology 放射學科學	IEC	IEC 60601-2-43	2019	Medical electrical equipment - Part 2-43:Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	原採認標準
1126	14 Radiology 放射學科學	IEC	IEC 62471	2006	Photobiological safety of lamps and lamp systems	原採認標準
1127	14 Radiology 放射學科學	NEMA	XR 25 -2019	2019	Computed Tomography Dose Check	原採認標準
1128	14 Radiology 放射學科學	NEMA	NEMA MS 14	2019	Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems	原採認標準
1129	14 Radiology 放射學科學	IEC	IEC TR 63183	2019	Guidance on error and warning messages for software used in radiotherapy	原採認標準
1130	14 Radiology 放射學科學	AAMI	AAMI RT3	2020	Radiation therapy machine characterization	原採認標準
1131	14 Radiology 放射學科學	IEC	IEC 60336	2020	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics	原採認標準
1132	14 Radiology 放射學科學	IEC	IEC 62563-1	2021	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	原採認標準

1133	14 Radiology 放射學科學	IEC	IEC 61223-3-7	2021	Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography	原採認標準
1134	14 Radiology 放射學科學	NEMA	NEMA PS 3.1 - 3.20	2021	Digital Imaging and Communications in Medicine (DICOM) Set	原採認標準
1135	14 Radiology 放射學科學	IEC	IEC 62563-2	2021	Medical electrical equipment - Medical image display systems - Part 2: Acceptance and constancy tests for medical image displays	原採認標準
1136	14 Radiology 放射學科學	IEC	60601-2-33 Edition 4.0 2022-08	2022	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	113 年度新增採認標準
1137	14 Radiology 放射學科學	IEC	60806 Edition 2.0 2022-11	2022	Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis	113 年度新增採認標準
1138	14 Radiology 放射學科學	NEMA	PS 3.1 - 3.20 2022d	2022	Digital Imaging and Communications in Medicine (DICOM) Set	113 年度新增採認標準
1139	14 Radiology 放射學科學	IEC	60601-2-43 Edition 3.0 2022-12	2022	Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures	113 年度新增採認標準
1140	14 Radiology 放射學科學	IEC	60601-2-54 Edition 2.0 2022-09	2022	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and	113 年度新增採認標準

					radioscopy	
1141	14 Radiology 放射學科學	ISO	12005 Third edition 2022-05	2022	Lasers and laser-related equipment - Test methods for laser beam parameters - Polarization	113 年度新增採認標準
1142	15 Sterility 滅菌	ISO	ISO 14644-4	2001	Cleanrooms and Associated Controlled Environments - Part 4: Design, Construction and Start-up	原採認標準
1143	15 Sterility 滅菌	ISO	ISO 14698-1	2003	Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods	原採認標準
1144	15 Sterility 滅菌	ISO	ISO 14698-2	2003	Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 2: Evaluation and Interpretation of Biocontamination Data	原採認標準
1145	15 Sterility 滅菌	ISO	ISO 13408-4	2005	Aseptic processing of health care products —Part 4: Clean-in-place technologies	原採認標準
1146	15 Sterility 滅菌	ISO	ISO 14644-5	2004	Cleanrooms and associated controlled environments —Part 5: Operations	原採認標準
1147	15 Sterility 滅菌	ISO	ISO 14644-7	2004	Cleanrooms and associated controlled environments —Part 7: Separative devices (clean air hoods, gloveboxes, isolators and minienvironments)	原採認標準
1148	15 Sterility 滅菌	ISO	ISO 11140-3	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
1149	15 Sterility 滅菌	ISO	ISO 11140-4	2007	Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for	原採認標準

					detection of steam penetration	
1150	15 Sterility　滅菌	ISO	ISO 11140-5	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
1151	15 Sterility　滅菌	ISO	ISO 13408-3	2006	Aseptic processing of health care products -- Part 3: Lyophilization	原採認標準
1152	15 Sterility　滅菌	ISO	ISO 13408-5	2006	Aseptic processing of health care products -- Part 5: Sterilization in place	原採認標準
1153	15 Sterility　滅菌	CEN	EN 556-1	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
1154	15 Sterility　滅菌	ISO	ISO 17665-1	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
1155	15 Sterility　滅菌	ISO	ISO 14937	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
1156	15 Sterility　滅菌	ISO	ISO 15882	2008	Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results	原採認標準
1157	15 Sterility　滅菌	ISO	ISO/TS 17665-2	2009	Sterilization of health care products -- Moist heat --	原採認標準

					Part 2: Guidance on the application of ISO 17665-1	
1158	15 Sterility　滅菌	AOAC	AOAC6.2.02	2006	Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method	原採認標準
1159	15 Sterility　滅菌	AOAC	AOAC6.2.03	2006	Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method	原採認標準
1160	15 Sterility　滅菌	AOAC	AOAC6.2.05	2006	Testing Disinfectants Against Pseudomonas aeruginosa,Hard Surface Carrier Test Method.	原採認標準
1161	15 Sterility　滅菌	AOAC	AOAC6.3.02	2006	Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes.	原採認標準
1162	15 Sterility　滅菌	AOAC	AOAC6.3.05	2012	Sporicidal Activity of Disinfectants Method I.	原採認標準
1163	15 Sterility　滅菌	AOAC	AOAC6.3.06	2012	Tuberculocidal Activity of Disinfectants.	原採認標準
1164	15 Sterility　滅菌	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
1165	15 Sterility　滅菌	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
1166	15 Sterility　滅菌	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
1167	15 Sterility　滅菌	CNS	CNS 15691-2	2013	健康照護產品之無菌操作－第 2 部：過濾 Aseptic	原採認標準

					processing of health care products − Part 2: Filtration (IDE ISO 13408-2:2006)	
1168	15 Sterility　滅菌	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
1169	15 Sterility　滅菌	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
1170	15 Sterility　滅菌	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
1171	15 Sterility　滅菌	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
1172	15 Sterility　滅菌	ISO	ISO 13408-6	2021	Aseptic processing of health care products — Part 6: Isolator systems	原採認標準
1173	15 Sterility　滅菌	ISO	ISO 14160	2020	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 process for medical devices	原採認標準
1174	15 Sterility　滅菌	ISO	ISO 14644-8	2013	Cleanrooms and associated controlled environments -- Part 8: Classification of air cleanliness by chemical	原採認標準

					concentration (ACC)	
1175	15 Sterility　滅菌	ISO	ISO/ASTM 52701	2013	Guide for performance characterization of dosimeters and dosimetry systems for use in radiation processing	原採認標準
1176	15 Sterility　滅菌	AAMI	AAMI TIR35	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
1177	15 Sterility　滅菌	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
1178	15 Sterility　滅菌	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
1179	15 Sterility　滅菌	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
1180	15 Sterility　滅菌	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
1181	15 Sterility　滅菌	CNS	CNS 14622-5	2014	健康照護產品滅菌－生物指示劑－第 5 部：低溫	原採認標準

					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)	
1182	15 Sterility　滅菌	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
1183	15 Sterility　滅菌	EN	EN 14180	2014	Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	原採認標準
1184	15 Sterility　滅菌	EN	EN 1422	2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	原採認標準
1185	15 Sterility　滅菌	EN	EN 16615	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
1186	15 Sterility　滅菌	EN	EN 556-2	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

1187	15 Sterility　滅菌	ISO	ISO 11138-1	2017	Sterilization of health care products — Biological indicators Part 1: General requirements	原採認標準
1188	15 Sterility　滅菌	ISO	ISO 11138-2	2017	Sterilization of health care products — Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes	原採認標準
1189	15 Sterility　滅菌	ISO	ISO 11138-3	2017	Sterilization of health care products - Biological indicators Part 3: Biological indicators for moist heat sterilization processes	原採認標準
1190	15 Sterility　滅菌	ISO	ISO 11138-4	2017	Sterilization of health care products - Biological indicators Part 4: Biological indicators for dry heat sterilization processes	原採認標準
1191	15 Sterility　滅菌	ISO	ISO 11138-5	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
1192	15 Sterility　滅菌	ISO	ISO 11140-1	2014	Sterilization of health care products -- Chemical indicators -- Part 1: General requirements	原採認標準
1193	15 Sterility　滅菌	ISO	ISO 13408-7	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
1194	15 Sterility　滅菌	ISO	ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration - Second Edition	原採認標準
1195	15 Sterility　滅菌	ISO	ISO 14644-2	2015	Cleanrooms and Associated Controlled Environments	原採認標準

					- Part 2: Specification for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1	
1196	15 Sterility　滅菌	ISO	ISO 20857	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
1197	15 Sterility　滅菌	ISO	ISO/TS 16775	2014	Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	原採認標準
1198	15 Sterility　滅菌	ISO	ISO 11137-2	2013	Sterilization of health care products - Radiation Part 2: Establishing the sterilization dose	原採認標準
1199	15 Sterility　滅菌	ISO	ISO 13408-1	2013	Aseptic processing of health care products Part 1: General requirements	原採認標準
1200	15 Sterility　滅菌	AAMI	AAMI ST55	2016	Table-Top Steam Sterilizers	原採認標準
1201	15 Sterility　滅菌	ISO	ISO 11737-1	2018	Sterilization of medical devices -- Microbiological methods -- Part 1:Determination of a population of microorganisms on products	原採認標準
1202	15 Sterility　滅菌	ISO	ISO 13408-2	2018	Aseptic Processing of Health Care Products - Part 2: Filtration	原採認標準
1203	15 Sterility　滅菌	AAMI	AAMI ST50	2018	Dry heat (heated air) sterilizers	原採認標準
1204	15 Sterility　滅菌	AAMI	AAMI ST8	2018	Hospital steam sterilizers	原採認標準
1205	15 Sterility　滅菌	AAMI	AAMI ST24	2018	Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	原採認標準

1206	15 Sterility　滅菌	AAMI	AAMI ST77	2018	Containment devices for reusable medical device sterilization, 2nd ed.	原採認標準
1207	15 Sterility　滅菌	ISO	ISO 18472	2018	Sterilization of health care products —Biological and chemical indicators —Test equipment	原採認標準
1208	15 Sterility　滅菌	ISO	ISO 11138-7	2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results	原採認標準
1209	15 Sterility　滅菌	ASTM	ASTM F2315	2018	Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels	原採認標準
1210	15 Sterility　滅菌	ASTM	ASTM F2450	2018	Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products	原採認標準
1211	15 Sterility　滅菌	ISO	ISO 11135	2018	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	原採認標準
1212	15 Sterility　滅菌	ISO	ISO 11607-1	2019	Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems	原採認標準
1213	15 Sterility　滅菌	ISO	ISO 11607-2	2019	Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes	原採認標準
1214	15 Sterility　滅菌	ISO	ISO 11137-1	2018	Sterilization of health care products - Radiation Part 1: Requirements for development, validation and	原採認標準

					routine control of a sterilization process for medical devices	
1215	15 Sterility　滅菌	ISO	ISO 14644-3	2019	Cleanrooms and associated controlled environments —Part 3: Test methods	原採認標準
1216	15 Sterility　滅菌	ISO	ISO 11737-2	2019	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	原採認標準
1217	15 Sterility　滅菌	ISO	ISO/ASTM 52628	2020	Practice for dosimetry in radiation processing	原採認標準
1218	15 Sterility　滅菌	ASTM	F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	原採認標準
1219	15 Sterility　滅菌	ANSI AAMI	ST72	2019	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	原採認標準
1220	15 Sterility　滅菌	ASTM ISO	ISO/ASTM 51276	2019	Practice for use of a polymethylmethacrylate dosimetry system	原採認標準
1221	15 Sterility　滅菌	EN ISO	EN ISO 25424	2019	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	原採認標準
1222	15 Sterility　滅菌	ASTM	F2475	2020	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	原採認標準
1223	15 Sterility　滅菌	ASTM	ASTM F2097	2020	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	原採認標準

1224	15 Sterility　滅菌	ASTM ISO	ASTM ISO 51818	2020	Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV	原採認標準
1225	15 Sterility　滅菌	ASTM	ASTM F3004	2020	Standard Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound	原採認標準
1226	15 Sterility　滅菌	ASTM	ASTM F17	2020	Standard Terminology Relating to Flexible Barrier Packaging	原採認標準
1227	15 Sterility　滅菌	ANSI AAMI	ANSI AAMI ST79	2020	(Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities	原採認標準
1228	15 Sterility　滅菌	ISO	ISO 11138-8	2021	Sterilization of health care products - Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator	原採認標準
1229	15 Sterility　滅菌	ISO	ISO 17664-2	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.	原採認標準
1230	15 Sterility　滅菌	ASTM	ASTM F1608	2021	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	原採認標準
1231	15 Sterility　滅菌	ASTM	ASTM F88/F88M	2021	Standard Test Method for Seal Strength of Flexible Barrier Materials	原採認標準
1232	15 Sterility　滅菌	ASTM	ASTM D4169	2022	Standard Practice for Performance Testing of Shipping Containers and Systems	原採認標準

1233	15 Sterility　滅菌	ANSI AAMI	ANSI AAMI ST91	2021	Flexible and semi-rigid endoscope processing in health care facilities	原採認標準
1234	15 Sterility　滅菌	ISO	ISO 17664-1	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices	原採認標準
1235	15 Sterility　滅菌	CEN	EN 285	2021	Sterilization - Steam sterilizers - Large sterilizers	原採認標準
1236	15 Sterility　滅菌	CEN	EN ISO 17664-1	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)	原採認標準
1237	15 Sterility　滅菌	AAMI	AAMI TIR28	2016	Product Adoption And Process Equivalence For Ethylene Oxide Sterilization	原採認標準
1238	15 Sterility　滅菌	ANSI AAMI	ANSI AAMI 13959	2014	Water For Hemodialysis and Related Therapies	原採認標準
1239	15 Sterility　滅菌	AAMI	AAMI TIR43	2011	Ultrapure Dialysate For Hemodialysis And Related Therapies	原採認標準
1240	15 Sterility　滅菌	CEN	EN ISO 25424/A1	2022	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1	113 年度新增採認標準
1241	15 Sterility　滅菌	ISO	22441 First	2022	Sterilization of health care products - Low	113 年度新增採認

			edition 2022-08		temperature vaporized hydrogen peroxide - Requirements for the development validation and routine control of a sterilization process for medical devices	標準
1242	15 Sterility　滅菌	AAMI	/TIR17:2017/(R)2020	2022	Compatibility of materials subjected to sterilization	113 年度新增採認標準
1243	15 Sterility　滅菌	ASTM	F2391-22	2022	Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas	113 年度新增採認標準
1244	15 Sterility　滅菌	ISO	/TS 16775 Second edition 2021-11	2021	Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	113 年度新增採認標準
1245	15 Sterility　滅菌	ASTM	F2638-22	2022	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier	113 年度新增採認標準
1246	15 Sterility　滅菌	ISO	11137-2 Third edition 2013-06 [Including AMD1:2022]	2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]	113 年度新增採認標準
1247	15 Sterility　滅菌	ISO	TS 11137-4 First edition 2020-06	2020	Sterilization of health care products - Radiation - Part 4: Guidance on process control	113 年度新增採認標準
1248	15 Sterility　滅菌	ANSI AAMI	ST98:2022	2022	Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices	113 年度新增採認標準
1249	15 Sterility　滅菌	ASTM	F1980-21	2021	Standard Guide for Accelerated Aging of Sterile	113 年度新增採認

					Barrier Systems for Medical Devices	標準
1250	15 Sterility 滅菌	AAMI	/TIR104:2022	2022	Guidance on transferring health care products between radiation sterilization sources	113 年度新增採認標準
1251	16 Tissue Engineering 組織工程	ASTM	ASTM F2603	2020	Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds	原採認標準
1252	16 Tissue Engineering 組織工程	ISO	ISO 22442-2	2020	Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling	原採認標準
1253	16 Tissue Engineering 組織工程	ISO	ISO 22442-3	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
1254	16 Tissue Engineering 組織工程	ASTM	ASTM F2064	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
1255	16 Tissue Engineering 組織工程	ASTM	ASTM F3206	2017	Standard Guide for Assessing Medical Device Cytocompatibility with Delivered Cellular Therapies	原採認標準
1256	16 Tissue Engineering 組織工程	ASTM	ASTM F3207	2017	Standard Guide for in vivo Evaluation of Rabbit Lumbar Intertransverse Process Spinal Fusion Model	原採認標準
1257	16 Tissue	ASTM	ASTM F3224	2017	Standard Test Method for Evaluating Growth of	原採認標準

	Engineering 組織工程				Engineered Cartilage Tissue using Magnetic Resonance Imaging.	
1258	16 Tissue Engineering 組織工程	ASTM	ASTM F2212	2020	Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)	原採認標準
1259	16 Tissue Engineering 組織工程	ASTM	F2150	2019	Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Regenerative Medicine and Tissue-Engineered Medical Products	原採認標準
1260	16 Tissue Engineering 組織工程	ASTM	F2739	2019	Standard Guide for Quantifying Cell Viability and Related Attributes within Biomaterial Scaffolds	原採認標準
1261	16 Tissue Engineering 組織工程	ISO	ISO 22442-1	2020	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	原採認標準
1262	17 Neurology 神經科學	ISO	ISO 7197	2007	Technical Corrigendum1- Neurosurgical implants -- Sterile, single-use hydrocephalus shunts and components	原採認標準
1263	17 Neurology 神經科學	IEC	IEC 60601-2-23	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
1264	17 Neurology 神經科學	IEC	IEC 60601-2-10	2016	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential	原採認標準

					performance of nerve and muscle stimulators	
1265	17 Neurology 神經科學	ASTM	ASTM F647	2014	Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application	原採認標準
1266	17 Neurology 神經科學	AAMI	AAMI NS4	2017	Transcutaneous electrical nerve stimulators	原採認標準
1267	18 Nanotechnology 奈米科技	ISO	ISO 29701	2010	Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems—Limulus amebocyte lysate (LAL) test.	原採認標準
1268	18 Nanotechnology 奈米科技	ISO	ISO/TR 13014	2012	Nanotechnologies—Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment	原採認標準
1269	18 Nanotechnology 奈米科技	ISO	ISO 21363	2020	Nanotechnologies - Measurements of particle size and shape distributions by transmission electron microscopy	原採認標準
1270	18 Nanotechnology 奈米科技	ASTM	ASTM E3247	2020	Standard Test Method for Measuring the Size of Nanoparticles in Aqueous Media Using Dynamic Light Scattering	原採認標準
1271	18 Nanotechnology 奈米科技	ISO	ISO 19749	2021	Nanotechnologies - Measurements of particle size and shape distributions by scanning electron microscopy	原採認標準
1272	18 Nanotechnology 奈米科技	ASTM	ASTM E3275	2021	Standard Guide for Visualization and Identification of Nanomaterials in Biological and Nonbiological Matrices Using Darkfield Microscopy/Hyperspectral	原採認標準

					Imaging (DFM/HSI) Analysis	
1273	18 Nanotechnology 奈米科技	ASTM	E3025-22	2022	Standard Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles	113 年度新增採認標準
1274	18 Nanotechnology 奈米科技	ISO	/TS 80004-6 Second edition 2021-03	2021	Nanotechnologies - Vocabulary - Part 6: Nano-object characterization	113 年度新增採認標準
1275	18 Nanotechnology 奈米科技	ISO	17200 First edition 2020-09	2020	Nanotechnology - Nanoparticles in powder form - Characteristics and measurements	113 年度新增採認標準
1276	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	CNS	CNS 14912	2005	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
1277	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	CNS	CNS 14913	2005	醫電設備之圖形符號 (Graphical symbols for electrical equipment in medical practice)	原採認標準
1278	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1	2021	Interpretation Sheet 1 - Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	原採認標準
1279	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-2	2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	原採認標準

1280	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-6	2020	Amendment 2 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	原採認標準
1281	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-8	2020	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	原採認標準
1282	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 61326-1	2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	原採認標準
1283	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-10	2020	Amendment 2 - 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
1284	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-11	2020	Amendment 1 - 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	原採認標準

					healthcare environment	
1285	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-12	2020	Amendment 1 - 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
1286	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC TR 60601-4-2	2016	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
1287	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC/TR 62354	2014	General testing procedures for medical electrical equipment	原採認標準
1288	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEEE	IEEE/ANSI C63.27	2017	American National Standard for Evaluation of Wireless Coexistence	原採認標準
1289	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC/TR 60601-4-1	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
1290	19 General II	ANSI	ANSI AAMI	2021	Medical electrical equipment - Part 1: General	原採認標準

	(ES/EMC) 通用(醫療電子/電磁相容)	AAMI	ES60601-1		requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]	
1291	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ANSI AAMI	ANSI AAMI HA60601-1-11	2021	Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]	原採認標準
1292	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ANSI UL	ANSI UL 61010-1	2019	Standard for Safety for Electrical Equipment For Measurement, Control and Laboratory Use; Part 1: General Requirements	原採認標準
1293	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	AIM	AIM Standard 7351731	2021	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard	原採認標準
1294	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ISO	ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer	原採認標準
1295	19 General II (ES/EMC) 通用	IEEE ANSI	USEMCSC C63.27-2021	2021	American National Standard for Evaluation of Wireless Coexistence	113 年度新增採認標準

	(醫療電子/電磁相容)					
1296	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	2017	Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)] - Note: This standard is recognized with relevant US national differences applied see reference #1 in Relevant FDA Guidance and/or Supportive Publication section	113 年度新增採認標準
1297	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.	113 年度新增採認標準
1298	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	BS EN	BS EN 50637:2017	2017	Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children	113 年度新增採認標準

附件 2、歷年廢除之原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，然該項標準已被廢除者。
2. 提供 104 年至 113 年廢除之醫療器材標準共 255 項如下表。

序號	標準類別	標準組織名稱	標準號碼	標準版本	標準名稱
1	1 Anesthesias 麻醉學	IEC	IEC 60601-3-1:1996	1996	Medical Electrical Equipment Part 3-1: Essential Performance Requirements for Transcutaneous Oxygen and Carbon Dioxide Partial Pressure Monitoring Equipment
2	1 Anesthesias 麻醉學	ISO	ISO 7767:1997	1997	Oxygen Monitors for Monitoring Patient Breathing Mixtures - Safety Requirements
3	1 Anesthesias 麻醉學	ISO	ISO 8382:1988	1988	Resuscitators Intended for Use with Humans
4	1 Anesthesias 麻醉學	ISO	ISO 9918:1993	1993	Capnometers for Use with Humans - Requirements
5	1 Anesthesias 麻醉學	ASTM	ASTM F920-93(R1999)	1993	Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans
6	1 Anesthesias 麻醉學	ASTM	ASTM F1100-90(R1997)	1990	Standard Specification for Ventilators Intended for Use in Critical Care
7	1 Anesthesias 麻醉學	ASTM	ASTM F1101-90(R2003)e1	2003	Standard Specification for Ventilators Intended for Use During Anesthesia
8	1 Anesthesias 麻醉學	ASTM	ASTM F1456-01	2001	Standard Specification for Minimum Performance and Safety Requirements for Capnometers
9	1 Anesthesias 麻醉學	ISO	ISO 10651-3:1997	1997	Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency

					medical services environment
10	1 Anesthesias 麻醉學	ISO	ISO 21647: 2004/Cor 1:2005	2005	Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors-Technical Corrigendum 1
11	1 Anesthesias 麻醉學	ISO	ISO 18779:2005	2005	Medical devices for conserving oxygen and oxygen mixtures - Particular requirements
12	1 Anesthesias 麻醉學	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
13	1 Anesthesias 麻醉學	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
14	1 Anesthesias 麻醉學	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
15	1 Anesthesias 麻醉學	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
16	1 Anesthesias 麻醉學	ASTM	ASTM F1850-00/(R)2005	2005	Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components
17	1 Anesthesias 麻醉學	EN	EN 13544-1:2007+A1:2009	2010	Respiratory therapy equipment - Part 1: Nebulizing systems and their components - Incorporates Amendment A1: 2009
18	1 Anesthesias 麻醉學	IEC	IEC 60601-2-13:2009	2009	Medical electrical equipment – Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems - Edition 3.1; Consolidated Reprint
19	1 Anesthesias 麻醉學	ISO	ISO 8359:1996/Amd 1:2012	2012	Oxygen Concentrators for Medical Use - Safety Requirements
20	2 Biocompatibility 生物相容性	ISO	ISO/TS 20993:2006	2006	Biological evaluation of medical devices -- Guidance on a risk-management process

21	3 Cardiovascular 心臟血管醫學	CEN	EN 14299:2004	2004	Non active surgical implants - Particular requirements for cardiac and vascular implants - Specific requirements for arterial stents
22	3 Cardiovascular 心臟血管醫學	CEN	EN 12006-1:1999	1999	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 1: Heart valve substitutes
23	3 Cardiovascular 心臟血管醫學	CEN	EN 12006-3:1998	1999	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices
24	3 Cardiovascular 心臟血管醫學	AAMI	AAMI DF80:2003	2003	Medical electrical equipment—Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)
25	3 Cardiovascular 心臟血管醫學	AAMI	AAMI EC11:1991(R2001)	2001	Diagnostic electrocardiographic devices
26	3 Cardiovascular 心臟血管醫學	IEC	IEC 60601-2-30:1999	1999	Medical electrical equipment- Part 2-30: Particular requirements for safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
27	3 Cardiovascular 心臟血管醫學	ISO	ISO 5841-1:1989	1989	Cardiac Pacemakers - Part 1 : Implantable Pacemakers
28	3 Cardiovascular 心臟血管醫學	AAMI	AAMI SP10:2002/A1:2003	2002	Manual, electronic, or automated sphygmomanometers
29	3 Cardiovascular 心臟血管醫學	AAMI	EC11:1991/(R)2007	1991	Diagnostic electrocardiographic devices
30	3 Cardiovascular 心臟血管醫學	ISO	ISO 9919:2005	2005	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
31	3 Cardiovascular 心	CEN	EN 1060-1:1995	1995	Specification for Non-invasive sphygmomanometers Part 1. General

	臟血管醫學				requirements
32	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2065-00e1/(R)2010	2010	Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials
33	3 Cardiovascular 心臟血管醫學	CEN	EN 1060-3:1997+A2:2009	2009	Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems
34	3 Cardiovascular 心臟血管醫學	CEN	EN 12006-2:1998+A1:2009	2009	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2:Vascular prostheses including cardiac valve conduits
35	3 Cardiovascular 心臟血管醫學	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)
36	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13294:1997	1997	Dental Handpieces - Dental Air-Motors
37	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7494:1996	1996	Dental Units
38	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7785-1:1997	1997	Part 1: High-Speed Air Turbine Handpieces
39	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7785-2:1995	1995	Part 2: Straight and Geared Angle Handpieces
40	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 1562:1993	1993	Dental Casting Gold Alloys
41	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 1563:1990	1990	Dental Alginate Impression Material

42	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 1564:1995	1995	Dental Aqueous Impression Materials Based on Agar
43	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6871-1:1994	1994	Dental base metal casting alloys Part 1: Cobalt-based alloys - TECHNICAL CORRIGENDUM 1:1998
44	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6871-2:1994	1994	Dental Base Metal Casting Alloys Part 2: Nickel-Based Alloys
45	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 11498:1997	1997	Dental Handpieces: Dental Low Voltage Electrical Motors
46	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13294:1997	1997	Dental Handpieces - Dental Air-Motors
47	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 8891:2000	1998	Dental Casting Alloys with Noble Metal Content of At Least 25% but less than 75%
48	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13716:1999	1999	Dentistry - Reversible-Irreversible Hydrocolloid Impression Material Systems
49	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9693:1999/Amd 1:2005	2005	Metal-ceramic dental restorative systems.
50	4 Dental/ENT 牙科學/耳鼻喉科學	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)
51	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9693-1:2012	2012	Dentistry — Compatibility testing — Part 1: Metal-ceramic systems - First Edition
52	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 14155-1	2003	Clinical investigation of medical devices for human subjects — Part 1: General requirements
53	5 General I (QS/RM)	ISO	ISO 14155-2	2003	Clinical investigation of medical devices for human subjects — Part 2:

	通用(品質管理系統/風險管理)				Clinical investigation plans
54	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO/TR 16142	2006	Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices
55	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS15013	2006	用於法規目的之醫療器材品質管理系統要求
56	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	IEC 62366:2007	2007	Medical devices - Application of usability engineering to medical devices
57	5 General I (QS/RM) 通用(品質管理系統/風險管理)	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)
58	5 General I (QS/RM) 通用(品質管理系統/風險管理)	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
59	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	AAMI TIR36:2007	2007	Validation of software for regulated processes
60	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院	ISO	ISO 595/1	1988	Reusable all-glass or metal-and-glass syringes for medical use - Part 1: Dimensions

	及個人使用裝置				
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	ISO	ISO 595/2	1987	Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements and tests
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	ASTM	ASTM F882-84(R2002)	1985	Standard Performance and Safety Specification for Cryosurgical Medical Instruments
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	ASTM	ASTM F2196-02	2002	Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices
64	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	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)
65	6 General Plastic Surgery/General Hospital 一般及整形	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

	外科手術/一般醫院及個人使用裝置				Medical Electrical systems (IDE IEC 60601-1-1)
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	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 Compatibility-Requirements and Tests (IDE IEC 60601-1-2)
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	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)
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	CNS	CNS 14624-1	2002	醫療用輸液設備－第一部分：玻璃點滴瓶
69	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	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
70	6 General Plastic Surgery/General	CNS	CNS 14624-5	2002	醫療用輸液設備—第五部份：量管型輸液套

	Hospital 一般及整形外科手術/一般醫院及個人使用裝置				
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	CNS	CNS 14624-6	2002	醫療用輸液設備—第六部份：點滴瓶之凍晶乾燥瓶塞
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	CNS	CNS 14624-7	2002	醫療用輸液設備—第七部份：鋁—塑膠組合成之點滴瓶蓋
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	IEC	IEC 60601-2-38:1996/Amd.1:1999	1999	Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds
74	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	ISO	ISO 594-1:1986	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
75	6 General Plastic	ISO	ISO 594-2:1998	1998	Conical fittings with a 6% (Luer) taper for syringes, needles and certain

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				other medical equipment - Part 2: Lock fittings
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	AAMI	II36:2004	2004	Medical electrical equipment - Part 2: Particular requirements for safety of baby incubators
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	CEN	EN 12470-5:2003	2003	Clinical thermometers —Part 5: Performance of infra-red ear thermometers (with maximum device)
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	CEN	EN 12470-3:2000	2000	Clinical thermometers —Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device
79	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	AAMI	ANSI/AAMI BF7:2012	2012	Blood transfusion micro-filters

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	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
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	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)
82	7 In Vitro Diagnostics 體外診斷醫療器材	CEN	EN 13640:2002	2002	Stability Testing of In Vitro Diagnostic Reagents
83	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS GP 10-A:1995	1995	Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline
84	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS GP19-A2:2001	2003	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition
85	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS NRSCL 8-A:1998	1998	Terminology and Definitions for use in NCCLS Documents; Approved Standard
86	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C12-A	1994	Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard (1994)
87	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C21-A	1992	Performance Characteristics for Devices Measuring PO2 and PCO2 in Blood Samples; Approved Standard (1992)
88	7 In Vitro Diagnostics	CLSI	C25-A	1997	Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related

	體外診斷醫療器材				Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline (1997)
89	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C27-A	1993	Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline (1993)
90	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C42-A	1996	Erythrocyte Protoporphyrin Testing; Approved Guideline (1996)
91	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H10-A2	1995	Solubility Test to Confirm the Presence of Sickling Hemoglobins - Second Edition; Approved Standard (1995)
92	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H14-A2	1990	Devices for Collection of Skin Puncture Blood Specimens - Second Edition; Approved Guideline (1990)
93	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA6-A	1997	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)
94	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA10-A	1996	Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline (1996)
95	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA17-A	1997	Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Neural Tube Defects; Approved Guideline (1997)
96	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA19-A	1997	Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (1997)
97	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	DI1-A2	1992	Glossary and Guidelines for Immunodiagnostic Procedures, Reagents and Reference Materials-Second Edition

98	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C29-A2	2000	Standardization of Sodium and Potassium Ion Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard (2000)
99	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C31-A2	2001	Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline - Second Edition (2001)
100	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	DI02-A2	1993	Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials - Second Edition; Approved Guideline
101	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H07-A3	2000	Procedure for Determining Packed Cell Volume by the Microhematocrit Method - Second Edition; Approved Standard - Third Edition
102	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H30-A2	2001	Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline Second Edition
103	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H51-A	2002	Assays of vonWillebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline
104	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	LA01-A2	1994	Assessing the Quality of Radioimmunoassay Systems - Second Edition; Approved Guideline
105	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	RS2-A	1998	The National Reference System for the Clinical Laboratory (NRSCL) Aspartate Aminotransferase (AST)
106	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	RS3-A	1987	The National Reference System for the Clinical Laboratory (NRSCL) Cholesterol
107	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	RS5-A2	1993	The National Reference System for the Clinical Laboratory (NRSCL) Total Protein
108	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	RS6-A	1989	The National Reference System for the Clinical Laboratory (NRSCL) Total Bilirubin

109	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	T/DM6-A	1997	Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997)
110	7 In Vitro Diagnostics 體外診斷醫療器材	CEN	EN 375:2001	2000	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
111	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA23-A	2004	Assessing the Quality of Immunoassay Systems: Radioimmunoassays, and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guidelines
112	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO/TR 18112:2006	2006	Clinical laboratory testing and in vitro diagnostic test systems─In vitro diagnostic medical devices for professional use─Summary of regulatory requirements for information supplied by the manufacturer
113	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C3-A4	2006	Preparation and Testing of Reagent Water in the Clinical Laboratory
114	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM12-A	2006	Diagnostic nucleic acid microarrays
115	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C38-A	1997	Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline
116	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H17-A	1998	Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard
117	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM4-A	1999	Quality Assurance for Immunocytochemistry; Approved Guideline
118	7 In Vitro Diagnostics 體外診斷醫療器材	CNS	CNS 15035:2006	1996	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
119	7 In Vitro Diagnostics 體外診斷醫療器材	ANSI	AST3-A	1999	Wellness Testing Using IVD Devices; Approved Guideline

120	7 In Vitro Diagnostics 體外診斷醫療器材	ANSI	AST4-A2	2005	Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition
121	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP10-A	1995	Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline
122	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M21-A	1999	Methodology for the Serum Bactericidal Test; Approved Guideline
123	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M31-S1	2004	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Informational Supplement
124	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M31-A2	2002	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard—Second Edition
125	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M32-P	2001	Evaluation of Lots of Dehydrated Mueller-Hinton Broth for Antimicrobial Susceptibility Testing; Proposed Guideline
126	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M6-A2	2006	Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard - Second Edition
127	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	ILA2-A2	2006	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
128	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP27-A2	2007	Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline - Second Edition
129	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP20-A2	2003	Fine-Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline-Second Edition
130	7 In Vitro Diagnostics	CLSI	H49-A	2004	Point-of-Care Monitoring of Anticoagulation Therapy; Approved

	體外診斷醫療器材				Guideline
131	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C30-A2	2002	Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities
132	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C28-A3	2008	How to Define and Determine Reference Intervals in the Clinical Laboratory
133	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP09-A2-IR	2010	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition (Interim Revision)
134	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM02-A2	2002	Immunoglobin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline - Second Edition
135	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H04-A6	2008	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Sixth Edition
136	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	POCT02-A	2008	Implementation Guide of POCT01 for Health Care Providers; Approved Guideline
137	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M31-A3	2008	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard - Third Edition
138	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA30-A	2008	Immunoassay Interference by Endogenous Antibodies; Approved Guideline
139	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM16-A	2006	Use of External RNA Controls in Gene Expression Assays; Approved Guideline
140	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP22-A3	2011	Quality Management System: Continual Improvement; Approved Guideline—Third Edition
141	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	AUTO13-A2	2003	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation,

					Operation, and Monitoring; Approved Guideline - Second Edition; Vol. 23; No. 4
142	8 Materials 材料	ISO	ISO 5832-8:1997	1997	Implants for surgery -- Metallic materials -- Part 8: Wrought cobalt-nickel-chromium-molybdenum- tungsten-iron alloy
143	8 Materials 材料	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）
144	8 Materials 材料	CNS	CNS 13382-24	1996	外科植入物–超高分子量聚乙烯（第一部分：粉狀）
145	8 Materials 材料	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）
146	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD5:2003	2007	Hemodialysis systems
147	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD16:2007	2007	Cardiovascular implants and artificial organs - Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators
148	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD17:2007	2007	Cardiovascular implants and artificial organs - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters
149	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD52:2004	2004	Dialysate for hemodialysis
150	9	AAMI	AAMI RD61:2006	2007	Concentrates for hemodialysis

	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學				
151	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD62:2006	2007	Water treatment equipment for hemodialysis applications
152	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8638:2010	2010	Cardiovascular implants and extracorporeal systems -- Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
153	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	RD5:2003/(R)2008	2008	Hemodialysis systems
154	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	RD52:2004/(R)2010 (incl A1 through A4)	2010	Dialysate for hemodialysis (consolidated text with Amendments 1 through 4 included)
155	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 13959:2014	2014	Water for haemodialysis and related therapies - Third Edition
156	9	ISO	ISO 26722:2014	2014	Water treatment equipment for haemodialysis applications and related

	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學				therapies - Second Edition
157	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI 23500:2014	2014	Guidance for the preparation and quality management of fluids for hemodialysis and related therapies
158	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	CEN	EN 1283:1996	1996	Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits
159	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8637:2010/Amd 1:2013	2013	Revision to Figure 2 -- Main fitting dimensions of dialysis fluid inlet and outlet ports
160	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	EN	EN 1618:1997	1997	Catheters Other than Intravascular Catheters - Test Methods for Common Properties
161	10 Ophthalmic 眼科學	ISO	ISO 10338:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of curvature
162	10 Ophthalmic 眼科學	ISO	ISO 10339:1997	1997	Ophthalmic optics -- Contact lenses -- Determination of water content of hydrogel lenses
163	10 Ophthalmic 眼科	ISO	ISO 10340:1995	1995	Optics and optical instruments -- Contact lenses -- Method for

	學				determining the extractable substances
164	10 Ophthalmic 眼科學	ISO	ISO 10344:1996	1996	Optics and optical instruments -- Contact lenses -- Saline solution for contact lens testing
165	10 Ophthalmic 眼科學	ISO	ISO 9913-1:1996	1996	Optics and optical instruments -- Contact lenses -- Part 1: Determination of oxygen permeability and transmissibility with the FATT method
166	10 Ophthalmic 眼科學	ISO	ISO 9913-2:2000	2000	Optics and optical instruments -- Contact lenses -- Part 2: Determination of oxygen permeability and transmissibility by the coulometric method
167	10 Ophthalmic 眼科學	ISO	ISO 8321-1:2002	2002	Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 1: Rigid corneal and scleral contact lenses
168	10 Ophthalmic 眼科學	ISO	ISO 8321-2:2000	2000	Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 2: Single-vision hydrogel contact lenses
169	10 Ophthalmic 眼科學	ISO	ISO 8599:1994	1994	Optics and optical instruments -- Contact lenses -- Determination of the spectral and luminous transmittance
170	10 Ophthalmic 眼科學	ISO	ISO 9337-1:1999	1999	Contact lenses -- Determination of back vertex power -- Part 1: Method using focimeter with manual focusing
171	10 Ophthalmic 眼科學	ISO	ISO 9338:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of the diameters
172	10 Ophthalmic 眼科學	ISO	ISO 9339-1:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of the thickness -- Part 1: Rigid contact lenses
173	10 Ophthalmic 眼科學	ISO	ISO 9339-2:1998	2000	Optics and optical instruments -- Contact lenses -- Determination of thickness -- Part 2: Hydrogel contact lenses
174	10 Ophthalmic 眼科	ISO	ISO 9340:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of

	學				strains for rigid contact lenses
175	10 Ophthalmic 眼科學	ISO	ISO 9341:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of inclusions and surface imperfections for rigid contact lenses
176	10 Ophthalmic 眼科學	ISO	ISO 9914:1995	1995	Optics and optical instruments -- Contact lenses -- Determination of refractive index of contact lens materials
177	10 Ophthalmic 眼科學	ANSI	ANSI Z80.20-2010	2010	Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemcial Properties
178	10 Ophthalmic 眼科學	ISO	ISO 11979-9:2006/Amd 1:2014	2014	Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses AMENDMENT 1 - First Edition
179	11 Orthopaedics 骨科學	CNS	CNS 13382-9	1995	外科植入物–骨髓內釘系統（第二部分：骨髓釘）
180	11 Orthopaedics 骨科學	CNS	CNS 13382-10	1995	外科植入物–骨科人工關節–基本需求
181	11 Orthopaedics 骨科學	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）
182	11 Orthopaedics 骨科學	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
183	11 Orthopaedics 骨科學	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
184	11 Orthopaedics 骨科學	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
185	11 Orthopaedics 骨科學	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

186	11 Orthopaedics 骨科學	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
187	11 Orthopaedics 骨科學	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
188	11 Orthopaedics 骨科學	CNS	CNS 13382-19	1995	外科植入物–骨板彎曲強度與勁度的測定
189	11 Orthopaedics 骨科學	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
190	11 Orthopaedics 骨科學	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
191	11 Orthopaedics 骨科學	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
192	11 Orthopaedics 骨科學	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
193	11 Orthopaedics 骨科學	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）
194	11 Orthopaedics 骨科學	CNS	CNS 13382-27	1996	外科植入物–骨針及骨線（第二部分：Ｓｔｅｉｎｍａｎｎ骨針–尺度）
195	11 Orthopaedics 骨科學	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）
196	11 Orthopaedics 骨科學	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）
197	11 Orthopaedics 骨科學	CNS	CNS 13382-30	1996	外科植入物–成人之股骨端固定用裝置

198	12 Physical Medicine 物理醫學科學	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
199	12 Physical Medicine 物理醫學科學	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
200	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO4-A	2001	Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard
201	13 Software/Informatics 軟體/醫療資訊	AAMI	ANSI/AAMI SW68:2001	2001	Medical device software—Software life cycle processes
202	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO1-A	2000	Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard
203	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO5-A	2001	Laboratory Automation: Electromechanical Interfaces; Approved Standard
204	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO7-A	2004	Laboratory Automation: Data Content for Specimen Identification; Approved Standard
205	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 1074-2006	2006	IEEE Standard for Developing a Software Project Life Cycle Process
206	13 Software/Informatics	CNS	CNS 14232	1998	醫療資訊通信協定第七層

	軟體/醫療資訊				
207	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI SW87:2012	2012	Application of quality management system concepts to medical device data systems
208	14 Radiology 放射學科學	IEC	IEC 60601-2-32:1994	1994	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Associated Equipment of X-ray Equipment (1994)
209	14 Radiology 放射學科學	IEC	IEC 60601-2-9:1996	1997	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
210	14 Radiology 放射學科學	ISO	ISO 11810-1:2005	2005	Optics and optical Instruments - Lasers and laser-related equipment - Test method for the laser-resistance of surgical drapes and/or patient-protective covers
211	14 Radiology 放射學科學	ISO	ISO 11146:1999	2005	Lasers and laser-related equipment - Test methods for laser beam parameters - Beam widths, divergence angle and beam propagation factor
212	14 Radiology 放射學科學	ISO	ISO 11254-1:2000	2000	Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 1: 1-on-1 test
213	14 Radiology 放射學科學	ISO	ISO 11254-2:2001	2001	Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 2: S-on-1 test
214	14 Radiology 放射學科學	CNS	CNS 14509-3	2001	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)
215	14 Radiology 放射學科學	IEC	IEC/TR 60825-5:2003 Ed. 2.0	2003	Safety of laser products - Part 5: Manufacturer's checklist for IEC 60825-1

216	14 Radiology 放射學科學	IEC	IEC/TR 60825-9 - Ed. 1.0	1999	Safety of laser products - Part 9: Compilation of maximum permissible exposure to incoherent optical radiation
217	14 Radiology 放射學科學	IEC	IEC/TR 60825-10 - Ed. 1.0	2002	Safety of laser products - Part 10: Application guidelines and explanatory notes to IEC 60825-1
218	14 Radiology 放射學科學	CNS	CNS 14176-1	2005	醫學數位影像及通信－第 1 部：簡介與概述
219	14 Radiology 放射學科學	CNS	CNS 14176-2	2005	醫學數位影像及通信－第 2 部：符合性
220	14 Radiology 放射學科學	CNS	CNS 14176-3	1998	醫學數位影像及通信－第 3 部：資訊物件定義
221	14 Radiology 放射學科學	CNS	CNS 14176-4	1998	醫學數位影像及通信－第 4 部：服務類別規格
222	14 Radiology 放射學科學	CNS	CNS 14176-5	1998	醫學數位影像及通信－第 5 部：資料結構及編碼
223	14 Radiology 放射學科學	CNS	CNS 14176-6	2005	醫學數位影像及通信－第 6 部：資料辭典
224	14 Radiology 放射學科學	CNS	CNS 14176-7	1998	醫學數位影像及通信－第 7 部：訊息交換
225	14 Radiology 放射學科學	CNS	CNS 14176-8	2005	醫學數位影像及通信－第 8 部：訊息交換之網路通信支援
226	14 Radiology 放射學科學	CNS	CNS 14176-9	1998	醫學數位影像及通信－第 9 部：訊息交換之點對點通信支援
227	14 Radiology 放射學科學	CNS	CNS 14176-10	2007	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

228	14 Radiology 放射學科學	CNS	CNS 14176-11	2007	醫學數位影像及通信－第 11 部：媒體儲存應用規範
229	14 Radiology 放射學科學	CNS	CNS 14176-12	2007	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
230	14 Radiology 放射學科學	CNS	CNS 14176-14	2007	醫學數位影像及通信－第 14 部：灰階標準顯示函數
231	14 Radiology 放射學科學	CNS	CNS 14176-15	2007	醫學數位影像及通信－第 15 部：安全規範
232	14 Radiology 放射學科學	CNS	CNS 14176-18	2008	醫學數位影像及通信－第 18 部：DICOM 永續物件之資訊網存取
233	14 Radiology 放射學科學	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 X-ray diagnostic imaging (IDT: IEC 61674:1997))
234	14 Radiology 放射學科學	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
235	14 Radiology 放射學科學	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)
236	14 Radiology 放射學科學	IEC	IEC 60601-2-26:2015	2015	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
237	14 Radiology 放射學	IEC	IEC	2006	Evaluation and routine testing in medical imaging departments – Part

	科學		61223-3-5:2004+Corr1:2006		3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment - Edition 1.0
238	15 Sterility 滅菌	ISO	ISO 11134：1994	1994	Sterilization of health care products - Requirements for validation and routine control-industrial moist heat sterilization.
239	15 Sterility 滅菌	ISO	ISO 11135：1994	1994	Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.
240	15 Sterility 滅菌	ISO	ISO 11137：1995, Amendment 1：2001	2001	Sterilization of Health Care Products - Requirements for Validation and Routine Control-Radiation Sterilization and Amendment 1
241	15 Sterility 滅菌	ISO	ISO 11607:2000	2003	Packaging for terminally sterilized medical devices
242	15 Sterility 滅菌	CNS	CNS 14709	2013	Sterilization of medical devices - Validation and routine control of sterilisation by irradiation (MOD ISO 11737)
243	15 Sterility 滅菌	AAMI	ST66:1999	1999	Sterilization of health care products Chemical indicators Part 2: Class 2 indicators for air removal test sheets and packs
244	15 Sterility 滅菌	ISO	ISO 11135-1:2007	2007	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
245	15 Sterility 滅菌	ISO	ISO/TS 11135-2:2008	2008	Sterilization of health care products -- Ethylene oxide -- Part 2: Guidance on the application of ISO 11135-1
246	16 Tissue Engineering 組織工程	ASTM	ASTM F2311-08	2008	Standard Guide for Classification of Therapeutic Skin Substitutes
247	16 Tissue Engineering 組織工程	ASTM	ASTM F2451-05/(R)2010	2010	Standard Guide for in vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage
248	17 Neurology 神經學	ASTM	ASTM F1542-94 (R2000)	1994	Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips

249	17 Neurology 神經學	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要求(Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators)
250	17 Neurology 神經學	AAMI	AAMI NS28:1988/(R)2015	2015	Intracranial Pressure Monitoring Devices
251	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-1：2000	2000	Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems.
252	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-4：2000	2000	Medical Electrical Equipment - Part 1: General requirements for safety; 4. Collateral Standard: Programmable electrical medical systems.
253	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	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
254	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ISO	ISO/TS 19218-2:2012	2012	Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes - First Edition
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	ASTM	ASTM F2119-07(2013)	2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants