醫療器材採認標準資料表

編號	DOH-000318
標準分類	ABC. 體外檢驗醫療器材
標準號碼	EN 375:2001
標準名稱	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
制定日期	2000/12/06
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Diagnosis (medical), Clinical investigation instruments, Reagent solutions, Instructions for use, Reagent bottles, Containers.
簡要說明	This standard specifies the requirements for the information supplied by the manufacturer of in vitro diagnostic reagents including reagent products, calibrators, control materials and kits for professional use, which hereafter are called IVD reagents.

醫療器材採認標準資料表

編號	DOH-000319
標準分類	ABC. 體外檢驗醫療器材
標準號碼	EN 13612:2002
標準名稱	Performance evaluation of in vitro diagnostic medical devices
制定日期	2002/01/05
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Performance testing of Clinical investigation instruments, Diagnostic testing
簡要說明	In particular, this standard applies to IVD MDs to - show evidence to notified bodies and national authorities by results of a performance evaluation that the IVD MD performs as claimed by the manufacturer, - establish adequate performance evaluation data originating from appropriate studies or resulting from available literature, and to - satisfy the requirements of a quality system for design validation.

醫療器材採認標準資料表

編號	DOH-000320
標準分類	ABC. 體外檢驗醫療器材
標準號碼	EN ISO 17511:2003
標準名稱	In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials
制定日期	2003-08-15
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Clinical investigation instruments, Measurement and Control samples
簡要說明	This European Standard specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, *in vitro* diagnostic medical devices. External quality assessment (survey) samples, with proven commutability, whose values have been assigned by means of internationally agreed reference measurement systems or internationally agreed conventional reference measurement systems fall within the scope of this European Standard.

醫療器材採認標準資料表

編號	DOH-000321
標準分類	ABC. 體外檢驗醫療器材
標準號碼	EN ISO 18153
標準名稱	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
制定日期	2003-08-15
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Clinical investigation instruments, Measurement and Control samples
簡要說明	This European Standard specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement of the catalytic concentration of enzymes. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, in vitro diagnostic medical devices.

醫療器材採認標準資料表

編號	DOH-000322
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM9-A
標準名稱	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline
制定日期	12/20/2004
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Nucleic Acid Sequencing
簡要說明	This document addresses automated, PCR-based, dideoxy-terminator, and primer extension sequencing done on gel- or capillary-based sequencers. Topics covered include specimen collection and handling; isolation of nucleic acid; amplification and sequencing of nucleic acids; interpretation and reporting results; and quality control/assessment considerations as appropriate.

醫療器材採認標準資料表

編號	DOH-000323
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H21-A4
標準名稱	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition
制定日期	12/01/2003
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays
簡要說明	This document contains procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and provides general recommendations for performing the tests

醫療器材採認標準資料表

編號	DOH-000324
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA23-A
標準名稱	Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline
制定日期	04/20/2004
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays
簡要說明	This guideline addresses components for harmonizing and assessing the quality of immunoassay systems for several commonly used dose-response indicator categories, e.g., radioisotopes, enzymes, fluorescence, luminescence, reagents, and experimental components criteria essential to characterizing an immunoassay.

醫療器材採認標準資料表

編號	DOH-000325
標準分類	ABC. 體外檢驗醫療器材
標準號碼	ISO/TR18112
標準名稱	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
制定日期	2006-01-13
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	IVD medical devices
簡要說明	ISO/TR 18112:2006 summarizes regulatory requirements and associated guidance for information supplied by the manufacturer with IVD medical devices intended for professional use. Information supplied by the manufacturer includes labels on the outer and immediate container as well as instructions for use. Current labelling regulations and regulatory guidance from Canada, the European Union, Japan and the United States are included. Labelling guidance from the Global Harmonization Task Force and proposed labelling regulations from Australia are included for comparison. IVD medical devices for self-testing are excluded.

醫療器材採認標準資料表

編號	DOH-000326
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C3-A4
標準名稱	Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline - Fourth Edition
制定日期	06/16/2006
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Preparation and Testing of Reagent Water in the Clinical Laboratory
簡要說明	This document provides guidelines on water purified for clinical laboratory use; methods for monitoring water quality and testing for specific contaminants; and water system design considerations.

醫療器材採認標準資料表

編號	DOH-000327
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C49-P
標準名稱	Analysis of Body Fluids in Clinical Chemistry; Proposed Guideline
制定日期	06/20/2006
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Analysis of Body Fluids in Clinical Chemistry
簡要說明	This document provides guidance for the application of widely available measurement procedures for testing body fluids and for reporting and interpreting those results. It emphasizes defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method verification for abnormal body fluid; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers. This document does not consider serum, plasma, whole blood, or fluids for which assays typically have performance claims in the measurement procedure documentation.

醫療器材採認標準資料表

編號	DOH-000328
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H56-A
標準名稱	Body Fluid Analysis for Cellular Composition; Approved Guideline
制定日期	07/10/2006
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Body Fluid Analysis for Cellular Composition
簡要說明	This guideline provides users with recommendations for collection and transport of body fluids, numeration and identification of cellular components, and guidance for qualitative and quantitative assessment of body fluid.

醫療器材採認標準資料表

編號	DOH-000329
標準分類	ABC. 體外檢驗醫療器材
標準號碼	I/LA2-A2
標準名稱	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
制定日期	03/22/2006
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens
簡要說明	This document addresses the criteria for ANA testing by immunofluorescence and by enzyme immunoassay, including test components, quantification of results, and classification criteria.

醫療器材採認標準資料表

編號	DOH-000330
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM10-P
標準名稱	Genotyping for Infectious Diseases: Identification and Characterization; Proposed Guideline
制定日期	06/08/2005
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Genotyping for Infectious Diseases
簡要說明	This guideline describes currently used analytical approaches and methodologies applied to identify the clinically important genetic characteristics responsible for disease manifestation, outcome, and response to therapy in the infectious disease setting. It also provides guidance on the criteria to be considered for design, validation, and determination of clinical utility of such testing.

醫療器材採認標準資料表

編號	DOH-000331
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM11-P
標準名稱	Molecular Methods for Bacterial Strain Typing; Proposed Guideline
制定日期	05/31/2006
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Molecular Methods for Bacterial Strain Typing
簡要說明	This guideline examines the biology behind molecular strain typing and the process of characterizing and validating typing systems. The prevalent methods are described with particular attention to pulsed-field gel electrophoresis (PFGE) and multilocus sequence typing (MLST).

醫療器材採認標準資料表

編號	DOH-000332
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM12-A
標準名稱	Diagnostic Nucleic Acid Microarrays; Approved Guideline
制定日期	05/30/2006
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Diagnostic Nucleic Acid Microarrays
簡要說明	This guideline provides recommendations for many aspects of the array process including: a method overview; nucleic acid extraction; the preparation, handling, and assessment of genetic material; quality control; analytic validation; and interpretation and reporting of results. A CLSI-IFCC joint project.

醫療器材採認標準資料表

編號	DOH-000333
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C38-A
標準名稱	Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline
制定日期	09/01/1997
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Control of Preanalytical Variation in Trace Element
簡要說明	This document contains guidelines for patient preparation, specimen collection, transport, and processing for the measurement of trace elements in a variety of biological matrices.

醫療器材採認標準資料表

編號	DOH-000334
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C39-A
標準名稱	A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard
制定日期	04/01/2000
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	A Designated Comparison Method for the Measurement of Ionized Calcium in Serum
簡要說明	This document describes a designated comparison method to standardize the ionized calcium measurements made by ion-selective electrode (ISE) potentiometry.

醫療器材採認標準資料表

編號	DOH-000335
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C43-A
標準名稱	Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs; Approved Guideline
制定日期	11/01/2002
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs
簡要說明	This document provides guidance on establishing uniform practices necessary to produce quality data for quantitation and identification of a drug or drug metabolite using the GC/MS method.

醫療器材採認標準資料表

編號	DOH-000336
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C44-A
標準名稱	Harmonization of Glycohemoglobin Measurements; Approved Guideline
制定日期	12/01/2002
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Harmonization of Glycohemoglobin Measurements
簡要說明	This document describes an established program to harmonize glycohemoglobin (GHB) testing results among laboratories to a common, outcomes-based reference system and includes recommendations for the clinical application of harmonized GHB testing results.

醫療器材採認標準資料表

編號	DOH-000337
標準分類	ABC. 體外檢驗醫療器材
標準號碼	C45-A
標準名稱	Measurement of Free Thyroid Hormones; Approved Guideline
制定日期	10/20/2004
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Measurement of Free Thyroid Hormones
簡要說明	This document addresses analytical and clinical validation of freee (nonprotein-bound) thyroid hormone (FTH) measurement procedures. An NCCLS-IFCC joint project.

醫療器材採認標準資料表

編號	DOH-000338
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H17-A
標準名稱	Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard
制定日期	12/01/1998
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Determination of Serum Iron, Total Iron-Binding Capacity
簡要說明	This document provides methods for determining serum iron and total iron-binding capacity; and describes the measurement of serum iron concentration as well as the determination of the percent saturation of transferrin with iron.

醫療器材採認標準資料表

編號	DOH-000339
標準分類	ABC. 體外檢驗醫療器材
標準號碼	H45-A2
標準名稱	Performance of the Bleeding Time Test; Approved Guideline- Second Edition.
制定日期	06/30/2005
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Performance of the Bleeding Time Test
簡要說明	This document contains guidelines for performing the template bleeding time test. A descriptive list of variables that can affect the results of the test is also included.

醫療器材採認標準資料表

編號	DOH-000340
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM4-A
標準名稱	Quality Assurance for Immunocytochemistry; Approved Guideline
制定日期	12/01/1999
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Quality Assurance for Immunocytochemistry
簡要說明	This document provides recommendations for the performance of immunocytochemical assays on cytologic and surgical pathology specimens. It is intended to promote a better understanding of the requirements, capabilities, and limitations of these diagnostic methods; to improve their intra- and inter-laboratory reproducibility; and to improve their positive and negative predictive values in the diagnosis of disease.

醫療器材採認標準資料表

編號	DOH-000341
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM6-A
標準名稱	Quantitative Molecular Methods for Infectious Diseases; Approved Guideline
制定日期	10/20/2003
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Quantitative Molecular Methods for Infectious Diseases
簡要說明	This document provides guidance for the development and use of quantitative molecular methods, such as nucleic acid probes and nucleic acid amplification techniques of the target sequences specific to partiular microgranisms. It also presents recommendations for quality assurance, proficiency testing, and interpreation of results.

醫療器材採認標準資料表

編號	DOH-000342
標準分類	ABC. 體外檢驗醫療器材
標準號碼	MM14-A
標準名稱	Proficiency Testing (External Quality Assessment) for Molecular Methods; Approved Guideline
制定日期	08/19/2005
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Proficiency Testing (External Quality Assessment) for Molecular Methods
簡要說明	This document provides guidelines for a quality proficiency testing program, including reliable databases; design control in the choice of materials and analytes; good manufacturing processes; documentation procedures; complaint handling; corrective and preventive action plans; and responsive timing of reports.

醫療器材採認標準資料表

編號	DOH-000343
標準分類	ABC. 體外檢驗醫療器材
標準號碼	POCT1-A
標準名稱	Point-of-Care Connectivity; Approved Standard
制定日期	December 2001
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Point-of-Care Connectivity
簡要說明	This standard establishes a set of specifications to allow seamless multivendor interoperability and communication between point-of-care devices, data concentrators, and clinical information systems. NCCLS document POCT1-A provides the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data concentrators, and laboratory information systems from a variety of vendors.

醫療器材採認標準資料表

編號	DOH-000344
標準分類	ABC. 體外檢驗醫療器材
標準號碼	AUTO3-A
標準名稱	Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard
制定日期	12/20/2000
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Laboratory Automation: Communication with Automated Systems
簡要說明	This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

醫療器材採認標準資料表

編號	DOH-000345
標準分類	ABC. 體外檢驗醫療器材
標準號碼	AUTO4-A
標準名稱	Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard
制定日期	03/20/2001
制定標準組織名稱	Clinical and Laboratory Standards Institute
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Laboratory Automation: Systems Operational Requirements
簡要說明	This document describes operational requirements, characteristics, and required information elements of clinical laboratory automation systems. This information is used to determine the status of a clinical specimen within the clinical laboratory automation system, as well as the status of the actual components of the clinical laboratory automation system.

醫療器材採認標準資料表

編號	DOH-000346
標準分類	2. 生物相容性
標準號碼	ISO 10993-18:2005
標準名稱	Biological evaluation of medical devices —Part 18: Chemical characterization of materials
制定日期	2005-07-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Chemical composition, Chemical properties, Metals, Alloys, Ceramics, Polymers.
簡要說明	ISO 10993-18:2005 describes a framework for the identification of a material and the identification and quantification of its chemical constituents. The chemical characterization information generated can be used for a range of important applications, for example, as part of an assessment of the overall biological safety of a medical device (ISO 10993-1 and 14971), as a measurement of the level of a leachable substance in a medical device in order to allow the assessment of compliance with the allowable limit derived for that substance from health based risk assessment (ISO 10993-17), for judging equivalence of a proposed material to a clinically established material, for judging equivalence of a final device to a prototype device to check the relevance of data on the latter to be used to support the assessment of the former, or for screening of potential new materials for suitability in a medical device for a proposed clinical application.

醫療器材採認標準資料表

編號	DOH-000347
標準分類	2. 生物相容性
標準號碼	ISO/TS 10993-19:2006
標準名稱	Biological evaluation of medical devices —Part 19: Physico-chemical, morphological and topographical characterization of materials
制定日期	2006-06-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Biological analysis and testing, Physico-chemical, morphological and topographical characterization of materials
簡要說明	ISO/TS 10993-19:2006 provides a compilation of parameters and test methods that can be useful for the identification and evaluation of the physico-chemical, morphological and topographical (PMT) properties of materials in finished medical devices. Such an assessment is limited to those properties that are relevant to biological evaluation and the medical device's intended use (clinical application and duration of use) even if such properties overlap with clinical effectiveness.

醫療器材採認標準資料表

編號	DOH-000348
標準分類	2. 生物相容性
標準號碼	ISO/TS 10993-20:2006
標準名稱	Biological evaluation of medical devices —Part 20: Principles and methods for immunotoxicology testing of medical devices
制定日期	2006-08-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Immunotoxicity of various types of medical devices.
簡要說明	ISO/TS 10993-20:2006 presents an overview of immunotoxicology with particular reference to the potential immunotoxicity of medical devices. It gives guidance on methods for testing for immunotoxicity of various types of medical devices. ISO/TS 10993-20:2006 is based on several publications written by various groups of immunotoxicologists over the last few decades in which the development of immunotoxicology as a separate entity within toxicology took place.

醫療器材採認標準資料表

編號	DOH-000349
標準分類	3. 滅菌
標準號碼	ISO11607-1:2006
標準名稱	Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems
制定日期	2006-04-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Packaging materials, Packaging for sterilized Medical equipment
簡要說明	ISO 11607-1:2006 specifies the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use. ISO 11607-1:2006 is applicable to industry, to health care facilities, and wherever medical devices are placed in sterile barrier systems and sterilized. ISO 11607-1:2006 does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements might also be necessary for drug/device combinations. ISO 11607-1:2006 does not describe a quality assurance system for control of all stages of manufacture.

醫療器材採認標準資料表

編號	DOH-000350
標準分類	3. 滅菌
標準號碼	ISO11607-2:2006
標準名稱	Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes
制定日期	2006-04-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Packaging materials, Packaging for sterilized Medical equipment
簡要說明	ISO 11607-2:2006 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems. ISO 11607-2:2006 is applicable to industry, to health care facilities, and wherever medical devices are packaged and sterilized. ISO 11607-2:2006 does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements may also be necessary for drug/device combinations.

醫療器材採認標準資料表

編號	DOH-000351
標準分類	3. 滅菌
標準號碼	ISO 13408-4:2005
標準名稱	Aseptic processing of health care products —Part 4: Clean-in-place technologies
制定日期	2005-11-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Medical devices or device components subjected to clean-in-place technologies
簡要說明	ISO 13408-4:2005 specifies the general requirements for clean-in-place (CIP) processes applied to product contact surfaces of equipment used in the manufacture of sterile health care products by aseptic processing and offers guidance on qualification, validation, operation and control. ISO 13408-4:2005 is applicable to processes where cleaning agents are delivered to the internal surfaces of equipment designed to be compatible with CIP, which may come in contact with the product. ISO 13408-4:2005 is not applicable to processes where equipment is dismantled and cleaned in a washer. ISO 13408-4:2005 does not supersede or replace national regulatory requirements, such as Good Manufacturing Practices (GMPs) and/or compendial requirements that pertain to particular national or regional jurisdictions.

醫療器材採認標準資料表

編號	DOH-000352
標準分類	3. 滅菌
標準號碼	ISO 13408-6:2005
標準名稱	Aseptic processing of health care products -- Part 6: Isolator systems
制定日期	2005-06-20
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Isolator systems
簡要說明	ISO 13408-6:2005 specifies the requirements for isolator systems used for aseptic processing and offers guidance on qualification, bio-decontamination, validation, operation and control of isolator systems used for aseptic processing of health care products. ISO 13408-6:2005 is focused on the use of isolator systems to maintain aseptic conditions; this may include applications for hazardous materials. ISO 13408-6:2005 does not supersede or replace national regulatory requirements, such as Good Manufacturing Practices (GMPs) and/or compendial requirements that pertain in particular to national or regional jurisdictions.

醫療器材採認標準資料表

編號	DOH-000353
標準分類	3. 滅菌
標準號碼	ISO 14644-3:2005
標準名稱	Cleanrooms and associated controlled environments — Part 3: Test methods
制定日期	2005-12-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Clean rooms, Environmental cleanliness, Air filters, Air cleaning equipment, Filtration.
簡要說明	ISO 14644-3:2005 specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones. Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational. ISO 14644-3:2005 is not applicable to the measurement of products or of processes in cleanrooms or separative devices.

醫療器材採認標準資料表

編號	DOH-000354
標準分類	3. 滅菌
標準號碼	ISO 14644-5:2004
標準名稱	Cleanrooms and associated controlled environments — Part 5: Operations
制定日期	2004-08-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Medical devices subjected to processing in controlled environments
簡要說明	ISO 14644-5:2004 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference should be made to ISO 14644-2 and ISO 14644-3 for monitoring particles, and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.

醫療器材採認標準資料表

編號	DOH-000355
標準分類	3. 滅菌
標準號碼	ISO 14644-7:2004
標準名稱	Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and minienvironments)
制定日期	2004-10-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Medical devices subjected to processing in controlled environments
簡要說明	ISO 14644-7:2004 specifies the minimum requirements for the design, construction, installation, test and approval of separative devices, in those respects where they differ from cleanrooms as described in ISO 14644-4 and 14644-5. The application of ISO 14644-7:2004 takes into account the following limitations: user requirements are as agreed by customer and supplier; application-specific requirements are not addressed; specific processes to be accommodated in the separative-device installation are not specified; fire, safety and other regulatory matters are not considered specifically; where appropriate, national and local regulations apply. ISO 14644-7:2004 is not applicable to full-suits.

醫療器材採認標準資料表

編號	DOH-000356
標準分類	3. 滅菌
標準號碼	ISO/FDIS 11137-1:2006
標準名稱	Sterilization of health care products —Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
制定日期	2006-03-12
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Radiation sterilization process for medical devices
簡要說明	ISO 11137-1:2006 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices. Although the scope of ISO 11137-1:2006 is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment. ISO 11137-1:2006 covers radiation processes employing irradiators using the radionuclide ^{60}Co or ^{137}Cs, a beam from an electron generator or a beam from an X-ray generator.

醫療器材採認標準資料表

編號	DOH-000357
標準分類	3. 滅菌
標準號碼	ISO/FDIS 11137-2:2006
標準名稱	Sterilization of health care products —Radiation — Part 2: Establishing the sterilization dose
制定日期	2006-03-12
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Radiation sterilization process for medical devices
簡要說明	ISO 11137-2:2006 specifies methods of determining the minimum dose needed to achieve a specified requirement for sterility and methods to substantiate the use of 25 kGy or 15 kGy as the sterilization dose to achieve a sterility assurance level (SAL) of 10^{-6}. It also specifies methods of dose auditing in order to demonstrate the continued effectiveness of the sterilization dose. ISO 11137-2:2006 defines product families for dose establishment and dose auditing.

醫療器材採認標準資料表

編號	DOH-000358
標準分類	3. 滅菌
標準號碼	ISO/FDIS 11137 -3:2006
標準名稱	Sterilization of health care products —Radiation — Part 3: Guidance on dosimetric aspects
制定日期	2006-03-12
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Radiation sterilization process for medical devices
簡要說明	ISO 11137-3:2006 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to dosimetry. Dosimetry procedures related to the development, validation and routine control of a radiation sterilization process are described.

醫療器材採認標準資料表

編號	DOH-000359
標準分類	3. 滅菌
標準號碼	ISO/FDIS 18472:2006
標準名稱	Sterilization of health care products —Biological and chemical indicators —Test equipment
制定日期	2006-04-16
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Biological and chemical indicators of Sterile equipment
簡要說明	ISO 18472:2006 specifies the requirements for test equipment to be used to test chemical and biological indicators for steam, ethylene oxide, dry heat and vaporized hydrogen peroxide processes for conformity to the requirements given in ISO 11140-1 for chemical indicators, or the requirements given in the ISO 11138 series for biological indicators. ISO 18472:2006 also provides informative methods useful in characterizing the performance of biological and chemical indicators for intended use and for routine quality control testing.

醫療器材採認標準資料表

編號	DOH-000360
標準分類	3. 滅菌
標準號碼	EN 556-1:2001
標準名稱	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
制定日期	2001/08/18
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Sterilized medical devices
簡要說明	This European Standard specifies the requirements for a terminally-sterilized medical device to be designated "STERILE". Part 2 of this European Standard specifies the requirements for an aseptically processed medical device to be designated "STERILE". NOTE For the purpose of the EU Directive(s) for medical devices (see Bibliography), designation of a medical device as "STERILE" is only permissible when a validated sterilization process has been applied. Requirements for validation and routine control of processes for the sterilization of medical devices are specified in EN 550, EN 552, EN 554, EN IS0 14160 and EN IS0 14937.

醫療器材採認標準資料表

編號	DOH-000361
標準分類	2. 生物相容性
標準號碼	ISO 10993-2:2006
標準名稱	Biological evaluation of medical devices -- Part 2: Animal welfare requirements
制定日期	2006-07-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Animal testing
簡要說明	ISO 10993-2:2006 is aimed at those who commission, design and perform tests or evaluate data from animal tests undertaken to assess the biocompatibility of materials intended for use in medical devices, or of the medical devices themselves. It specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made for the welfare of animals used in animal tests to assess the biocompatibility of materials used in medical devices. ISO 10993-2:2006 also makes recommendations and offers guidance intended to facilitate future further reductions in the overall number of animals used, refinement of test methods to reduce or eliminate pain or distress in animals, and the replacement of animal tests by other scientifically valid means not requiring animal tests. It applies to tests performed on living vertebrate animals, other than man, to establish the biocompatibility of materials or medical devices.

醫療器材採認標準資料表

編號	DOH-000362
標準分類	2. 生物相容性
標準號碼	ISO 10993-10:2002/ Amd 1:2006
標準名稱	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity
制定日期	2002-09-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Tests for irritation and delayed-type hypersensitivity
簡要說明	This part of ISO 10993 describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and delayed-type hypersensitivity. This part of ISO 10993 includes pretest considerations, details of the test procedures, and key factors for the interpretation of the results. Guidance is given in annex A for the preparation of materials specifically in relation to the above tests. Guidance on the conduct of supplementary tests which are required specifically for devices used intradermally and in the ocular area is given in annex B. Guidance on the conduct of supplementary tests which may be required for devices used for oral, rectal, penile and vaginal areas is given in annex C.

醫療器材採認標準資料表

編號	DOH-000363
標準分類	2.生物相容性
標準號碼	14393-1
標準名稱	醫療器材生物性評估－第1部分：評估與試驗
制定日期	93/04/20
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	所有接觸人體組織之醫療器材
簡要說明	本標準規定 (1) 醫療器材生物性評估之通則； (2) 依據與身體接觸之性質及時間長短的醫療器材分類； (3) 適當試驗方法的選擇。 備考：本標準未涵蓋使用時未直接或間接與身體接觸之材料及器材之試驗或是因機械故障造成之生物性危害

醫療器材採認標準資料表

編號	DOH-000364
標準分類	2. 生物相容性
標準號碼	14393-2
標準名稱	醫療器材生物性評估－第2部分：動物福利之規定
制定日期	93/04/20
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	動物實驗、實驗用動物
簡要說明	本標準規定在生物試驗時使用動物的最低要求。本標準適用於脊椎動物的實驗，但不適用於較未分化動物的實驗，或在分離的組織與器官上進行的實驗。本標準亦提供針對以下目的之建議：包括在生物相容性試驗時減少使用動物數目，與當可能時避免使用動物。本標準同時希望(1) 建立指引使科學家尊重生命；(2) 利用最佳化已進行的實驗，以減少動物實驗的次數與實驗中使用動物的數目；(3) 在實驗中讓使用的動物承受最少的痛苦及保持生命的品質。

醫療器材採認標準資料表

編號	DOH-000365
標準分類	2.生物相容性
標準號碼	14393-3
標準名稱	醫療器材生物性評估－第 3 部分：基因毒性、致癌性與生殖毒性之試驗
制定日期	93/04/20
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	所有接觸人體組織之醫療器材，可以吸收的材料與器材，子宮內器材或任何可能與生殖組織或胚胎（胎兒）長期直接接觸的器材。
簡要說明	本標準規定下列生物性試驗— 基因毒性；— 致癌性；— 生殖與發育毒性。這些生物性試驗與某些類別的醫療器材(參見備考)的生物性評估有關。某些種類醫療器材的生物性評估有其相互關聯，CNS 14393-1〔醫療器材生物性評估-第一部分：評估與試驗〕提供了選擇相關試驗之指引。該指引確定了潛在之基因毒性，致癌性或生殖毒性評估的必要性，這些特性應遵循本標準進行評估。此標準所涵蓋之大部分試驗是參考經濟合作暨發展組織(OECD)對化學品試驗之指引。當試驗參考相關之 OECD 指引時將註明” OECD 指引”及試驗方法之號碼。在執行試驗時，這些試驗必須依據現行的 OECD 指引執行。

醫療器材採認標準資料表

編號	DOH-000366
標準分類	2.生物相容性
標準號碼	14393-4
標準名稱	醫療器材生物性評估－第4部分：血液接觸特性測試方法的選擇
制定日期	93/04/20
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	血液接觸性醫療器材
簡要說明	本標準適用於評估醫療器材與接觸特性之一般規定。本標準涵蓋：(1) 依據CNS 14393-1〔醫療器材生物性評估-第一部分：評估與試驗〕所定義之用途及使用時間長短，對與血液接觸的醫療及牙科器材進行分類。(2) 基本原理用於評估醫療器材與血液接觸作用。(3) 依據特定分類結構性選擇測試之方法以及測試方法之基本科學原理。由於對血液與醫療器材交互作用之知識及其測試方法精密度的限制，無法對測試方法之細節詳細規定。本標準只對生物評估測試作通則性描述，可能無法完全針對某特定醫療器材測試方法提供足夠指引。除了依據CNS 14393-1〔醫療器材生物性評估-第一部分：評估與試驗〕規定外，另作下述之定義。

醫療器材採認標準資料表

編號	DOH-000367
標準分類	2.生物相容性
標準號碼	14393-5
標準名稱	醫療器材生物性評估 －第5部分：體外細胞毒性試驗
制定日期	93/04/20
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	所有直接或間接接觸人體組織之醫療器材
簡要說明	本標準規定評估醫療器材體外細胞毒性之試驗方法。這些方法指明細胞培養是直接或透過擴散作用(1) 與器材之萃取物，和(或)(2) 與器材接觸。這些方法是用適當之生物參數檢測哺乳類細胞體外之生物反應。

醫療器材採認標準資料表

編號	DOH-000368
標準分類	2.生物相容性
標準號碼	14393-9
標準名稱	醫療器材生物性評估－第 9 部：潛在降解產物之鑑別及定量分析架構
制定日期	94/03/25
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	生物可吸收性醫療器材
簡要說明	本標準適用於提供醫療器材潛在與觀測的生物降解系統性評估醫療器材及生物降解研究的設計與效能的通則。本標準不適用於：(1) 活體組織工程產品；(2) 以機械程序產生降解產物的研究方法。產生此種降解產物所採用的研究方法會在特定產品標準中描述；(3) 非降解產物的可溶出成分。產品標準提供適用的特定產品研究方法以鑑定及定量分析降解產物，那些標準應可視作另一種規範。

醫療器材採認標準資料表

編號	DOH-000369
標準分類	2.生物相容性
標準號碼	14393-13
標準名稱	醫療器材生物性評估－第13部：聚合物醫療器材降解產物之鑑別及定量
制定日期	94/03/25
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal　　☐ Vertical
影響產品或類別	可產生降解及可溶出物之聚合物醫療器材
簡要說明	本標準提供臨床上使用之聚合物醫療器材其降解產物定性及定量試驗之設計時所須遵循之一般規定指引。並規範兩種產生降解產物之方式：其一為作為篩選方式之加速降解試驗，另一種則為即時降解試驗。對於原位聚合之材料則取固化或硬化後之聚合物進行試驗。所產生之數據則使用於聚合物之生物性評估。本標準僅考慮聚合物醫療器材因化學變化所產生的降解產物，不適用於該器材在使用時因機械應力、磨耗或電磁輻射所產生的降解。碎片及可溶性降解產物之生物性活性並不在本標準的討論範圍，但是其評估方法應依CNS 14393-1〔醫療器材生物性評估-第1部：評估與試驗〕和ISO 14538〔Biological evaluation of medical devices –establishment of permissible limits for sterilization and process residues using health-based risk assessment〕的規定進行。由於在醫療器材中所使用的聚合物範圍廣泛，所以並未指定使用特定的分析技術。對於可接受的降解產物濃度，本標準並不提供特定要求。

醫療器材採認標準資料表

編號	DOH-000370
標準分類	2.生物相容性
標準號碼	14393-14
標準名稱	醫療器材生物性評估－第14部：陶瓷降解產物之鑑別及定量
制定日期	94/03/25
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	可產生降解及可溶出物之陶瓷醫療器材
簡要說明	本標準規定兩種方法來獲得陶瓷(包括玻璃)降解產物的溶液，作為定量分析用。本標準也定訂溶液分析的指引以便鑑別降解產物。因為本標準的一般性，當可取得產品更接近實際使用條件下之降解產物生成的特定標準時應優先予以考慮。本標準僅考量陶瓷在體外試驗過程中因陶瓷化學解離所產生的降解產物，不包括利用機械應力或外在能量引起的降解。CNS 13765〔牙科用陶瓷〕及ISO 9693[Metal-ceramic dental restorative systems]涵蓋化學降解試驗，但並未處理降解產物分析。因為使用在醫療器材上的陶瓷範圍及對結果的準確度與精密度的不同要求，所以並未指定特定的分析技術。此外，本標準對降解產物可接受的程度並未提出特定要求。雖然這些材料預定在生物醫學上應用，但本標準未規範這些降解產物的生物活性。

醫療器材採認標準資料表

編號	DOH-000371
標準分類	2.生物相容性
標準號碼	14393-15
標準名稱	醫療器材生物性評估－第15部：金屬及合金之降解產物的鑑別及定量
制定日期	95/06/01
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	可產生降解及可溶出物之金屬及合金醫療器材
簡要說明	本標準提供設計試驗方法一般規定的指引，用以鑑別及定量金屬醫療器材成品或預備作為臨床使用的材料樣品的降解產物。其僅適用於在體外加速降解試驗時，金屬器材成品經化學改變所產生的降解產物。由於這些試驗是加速性，試驗結果不會反映出植入物或材料在體內的行為。所述的化學方法是用以產生降解產物作為進一步評估的方法。本標準不適用於施加機械應力發生的降解產物。

醫療器材採認標準資料表

編號	DOH-000372
標準分類	2.生物相容性
標準號碼	14393-16
標準名稱	醫療器材生物性評估－第16部：降解產物與可溶出物毒性動力學之研究設計
制定日期	95/06/01
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	生物可吸收性醫療器材、永久植入性醫療器材或可能發生生物降解、腐蝕及可溶出物之醫療器材。
簡要說明	本標準適用於進行與醫療器材有關的毒性動力學研究時，所應當具備的設計與執行原理。

醫療器材採認標準資料表

編號	DOH-000373
標準分類	F. 牙科裝置
標準號碼	ANSI ADA Specification No.27:1997
標準名稱	Resin-Based Filling Materials
制定日期	1997
制定標準組織名稱	AMERICAN DENTAL ASSOCIATION (ADA)/ AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Tooth shade resin material
簡要說明	This Standard specifies requirements for dental resin-based restorative materials supplied in a form suitable for mechanical mixing, hand mixing, or external energy activation. This specification does not cover requirements for materials intended to prevent dental caries, or for materials that are cured outside the mouth.

醫療器材採認標準資料表

編號	DOH-000374
標準分類	F. 牙科裝置
標準號碼	ANSI ADA Specification No.96
標準名稱	Dental-Water-Based Cements - Adoption of ISO 9917:1991
制定日期	2000
制定標準組織名稱	AMERICAN DENTAL ASSOCIATION (ADA)/ AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Dental cements
簡要說明	This standard specifies requirements for certain types of dental cements, including both hand-mixed and capsulated cements for the mechanical mixing, that are intended for permanent cementation, lining and restoration, and that effect setting only by an aqueous acid-base reaction. This specification is an adoption of ISO 9917:1991, Dental Water-Based Cements.

醫療器材採認標準資料表

編號	DOH-000375
標準分類	F. 牙科裝置
標準號碼	EN 1639:1996
標準名稱	Dentistry - Medical devices for dentistry - Instruments
制定日期	1996/07/12
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental instruments.
簡要說明	This European Standard specifies general requirements for instruments used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer. This standard does not apply to any necessary energy source to which an instrument needs to be connected. These energy sources are covered by the level 2 and level 3 standards, for dental equipment. Tests for demonstrating compliance with this standard are contained in the level 3 standards, if appropriate.

醫療器材採認標準資料表

編號	DOH-000376
標準分類	F. 牙科裝置
標準號碼	EN 1640:1996
標準名稱	Dentistry - Medical devices for dentistry - Equipment
制定日期	1996/07/04
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental equipment.
簡要說明	This European Standard specifies general requirements for items of dental equipment used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, packaging, marking, labelling, and information supplied by the manufacturer. This standard does not include requirements for dental X-ray equipment. This standard does not apply to any dental instruments connected to an item of dental equipment. These instruments are covered by the level 2 and level 3 standards for dental instruments. Tests for demonstrating compliance with this standard are contained in the level 3 standards, if appropriate.

醫療器材採認標準資料表

編號	DOH-000377
標準分類	F. 牙科裝置
標準號碼	EN 1641:1996
標準名稱	Dentistry - Medical devices for dentistry - Materials
制定日期	1996/07/04
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental materials, Dental impression materials, Dental filling materials, Dental cements, Dentures.
簡要說明	This European Standard specifies general requirements for materials used in the practice of dentistry for the restoration of the form and function of the dentition and which are medical devices. For the purposes of this standard these materials are defined as restorative materials. Dental implants are specifically excluded and described in EN 1642. This standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer. Tests for demonstrating compliance with this standard are contained in the level 3 standards, if appropriate.

醫療器材採認標準資料表

編號	DOH-000378
標準分類	F. 牙科裝置
標準號碼	EN 1642:1996
標準名稱	Dentistry - Medical devices for dentistry - Dental implants
制定日期	1996/07/04
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental materials, Dentistry, Implants (surgical), Dental prosthesis.
簡要說明	This European Standard specifies general requirements for dental implants. Surgically implantable dental materials defined as restorative materials are specifically excluded and described in EN 1641. This standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

醫療器材採認標準資料表

編號	DOH-000379
標準分類	F. 牙科裝置
標準號碼	ISO 6360-1: 2004
標準名稱	Dentistry -- Number coding system for rotary instruments -- Part 1: General characteristics
制定日期	2004-04-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental instruments, Dental rotary-cutting instruments, Dental equipment.
簡要說明	ISO 6360-1:2004 presents a number coding system for dental rotary instruments and accessories, and provides guidance with regard to its interpretation and use. ISO 6360-1:2004 specifies the code numbers for materials used for the working parts of instruments, the coating and the binding of abrasives for instruments. This three-digit number forms the first group of three digits in the 15-digit overall number. ISO 6360-1:2004 further specifies the code numbers for shanks, handles, or bore diameter of unmounted instruments, and for the overall lengths of instruments. This three-digit number forms the second group of three (two plus one) digits in the 15-digit overall number.

醫療器材採認標準資料表

編號	DOH-000380
標準分類	F. 牙科裝置
標準號碼	ISO 6360-2: 2004
標準名稱	Dentistry -- Number coding system for rotary instruments -- Part 2: Shapes
制定日期	2004-11-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental instruments, Dental rotary-cutting instruments, Dental equipment.
簡要說明	ISO 6360-2:2004 specifies the code numbers for the shapes of all dental rotary instruments and for several accessories used in connection with these instruments. This three-digit number for shape description forms the third group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1. NOTE In addition to terms for rotary instruments and accessories used in two of the three official ISO languages (English, French and Russian), ISO 6360-2:2004 gives the equivalent terms in the German language: these are published under the responsibility of the member body for Germany (DIN). However, only the terms given in the official languages can be considered as ISO terms.

醫療器材採認標準資料表

編號	DOH-000381
標準分類	F. 牙科裝置
標準號碼	ISO 6360-3: 2005
標準名稱	Dentistry -- Number coding system for rotary instruments -- Part 3: Specific characteristics of burs and cutters
制定日期	2005-11-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental instruments, Dental rotary-cutting instruments, Dental equipment, Dental drills, Burrs (tools).
簡要說明	ISO 6360-3:2005 specifies the code numbers for specific characteristics of burs, finishing burs, cutters and surgical instruments, which refer to the type of toothing on the working part of the instrument. This three digit number appears in the locations 10 to 12 of the 15-digit overall number and forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and 6360-2. In addition to terms for rotary instruments and accessories used in two of the three official ISO languages (English, French and Russian), ISO 6360-3:2005 gives the equivalent terms in the German language; these are published under the responsibility of the member body for Germany (DIN). However, only the terms given in the official languages can be considered as ISO terms.

醫療器材採認標準資料表

編號	DOH-000382
標準分類	F. 牙科裝置
標準號碼	ISO 6360-4: 2004
標準名稱	Dentistry -- Number coding system for rotary instruments -- Part 4: Specific characteristics of diamond instruments
制定日期	2004-06-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dentistry-Diamond instruments
簡要說明	ISO 6360-4:2004 specifies the code numbers for specific characteristics of rotary diamond instruments and diamond-coated discs for use in dentistry. This three-digit number forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and ISO 6360-2. ISO 6360-4:2004 also gives a three-digit number which in addition to the 15-digit code number may be used to provide additional information for diamond instruments and diamond-coated discs, at the discretion of the manufacturer.

醫療器材採認標準資料表

編號	DOH-000383
標準分類	F. 牙科裝置
標準號碼	ISO 6360-6: 2004
標準名稱	Dentistry -- Number coding system for rotary instruments -- Part 6: Specific characteristics of abrasive instruments
制定日期	2004-06-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Rotary abrasive instruments used in dentistry.
簡要說明	ISO 6360-6:2004 specifies the code numbers for specific characteristics of rotary abrasive instruments used in dentistry. This three-digit number forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and ISO 6360-2. ISO 6360-6:2004 is also applicable to dental polishers which are considered as abrasive instruments.

醫療器材採認標準資料表

編號	DOH-000384
標準分類	F. 牙科裝置
標準號碼	ISO 6360-7: 2006
標準名稱	Dentistry – Number coding system for rotary instruments – Part 7: Specific characteristics of mandrels and special instruments
制定日期	2006-02-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Mandrels and special instruments such as bone cutters, implant burs, trephines, wax scrapers and polishers.
簡要說明	ISO 6360-7:2006 specifies the code numbers for specific characteristics of mandrels and special instruments such as bone cutters, implant burs, trephines, wax scrapers and polishers. This three-digit number forms the fourth group of three digits in the 15-digit overall number, the principles of which are explained in ISO 6360-1 and ISO 6360-2.

醫療器材採認標準資料表

編號	DOH-000385
標準分類	F. 牙科裝置
標準號碼	ISO 13397-1: 1995
標準名稱	Periodontal curettes, dental scalers and excavators -- Part 1: General requirements
制定日期	1995-l 2-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Periodontal curettes, Dental excavators, Curettes, Dental scalers.
簡要說明	Specifies the general material and performance requirements for periodontal curettes, dental scalers and excavators.

醫療器材採認標準資料表

編號	DOH-000386
標準分類	F. 牙科裝置
標準號碼	ISO 13397-2: 2005
標準名稱	Dentistry – Periodontal curettes, dental scalers and excavators – Part 2: Periodontal curettes of Gr-type
制定日期	2005-06-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Gr-type periodontal curettes.
簡要說明	ISO 13397-2:2005 specifies the designs and dimensions for Gr-type periodontal curettes.

醫療器材採認標準資料表

編號	DOH-000387
標準分類	F. 牙科裝置
標準號碼	ISO 13397-3: 1996
標準名稱	Periodontal curettes, dental scalers and excavators -- Part 3: Dental scalers -- H-type
制定日期	1996-09-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	H-type dental scalers
簡要說明	Gives the dimensions for H-type dental scalers.

醫療器材採認標準資料表

編號	DOH-000388
標準分類	F. 牙科裝置
標準號碼	ISO 13397-4: 1997
標準名稱	Periodontal curettes, dental scalers and excavators -- Part 4: Dental excavators -- Discoid-type
制定日期	1997-12-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental instruments, Dental excavators, Curettes, Dental scalers.
簡要說明	This part of ISO 13397 specifies the dimensions for dental excavators with discoid working ends.

醫療器材採認標準資料表

編號	DOH-000389
標準分類	F. 牙科裝置
標準號碼	ISO 15854:2005
標準名稱	Dentistry – Casting and baseplate waxes
制定日期	2005-07-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental casting wax and to dental baseplate wax.
簡要說明	ISO 15854:2005 is applicable to dental casting wax and to dental baseplate wax. It specifies the classification of, and requirements for, dental casting wax and baseplate wax together with the test methods to be employed to determine compliance with these requirements.

醫療器材採認標準資料表

編號	DOH-000390
標準分類	G. 耳鼻喉科用裝置
標準號碼	ASA S3.6-2004
標準名稱	Specification for Audiometers.
制定日期	2004/05/13
制定標準組織名稱	AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Audiometers
簡要說明	The audiometers covered in this specification are devices designed for use in determining the hearing threshold level of an individual in comparison with a chosen standard reference threshold level. This standard provides specifications and tolerances for pure tone, speech, and masking signals and describes the minimum test capabilities of different types of audiometers.

醫療器材採認標準資料表

編號	DOH-000391
標準分類	G. 耳鼻喉科用裝置
標準號碼	ASA S3.22:2003
標準名稱	Specification of Hearing Aid Characteristics.
制定日期	2003/08/28
制定標準組織名稱	AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Air-Conduction Hearing Aid Calibrator and Analysis System
簡要說明	The standard describes air conduction hearing-aid measurement methods that are particularly suitable for specification and tolerance purposes. Among the test methods described are output sound pressure level (SPL) with a 90-dB input SPL, full-on gain, frequency response, harmonic distortion, equivalent input noise, current drain, induction-coil sensitivity, and static and dynamic characteristics of automatic gain control (AGC) hearing aids. Specific configurations are given for measuring the input SPL to a hearing aid. Allowable tolerances in relation to values specified by the manufacturer are given for certain parameters. Appendices are provided to describe an equivalent substitution method, characteristics of battery simulators, and additional tests to characterize more completely the electroacoustic performance of hearing aids.

醫療器材採認標準資料表

編號	DOH-000392
標準分類	F. 牙科裝置
標準號碼	ISO 7405:1997
標準名稱	Dentistry -- Preclinical evaluation of biocompatibility of medical devices used in dentistry -- Test methods for dental materials
制定日期	1997- 08- 15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	All dental devices which enter the oral cavity
簡要說明	This International Standard specifies methods for the evaluation of biological effects of dental materials. It includes testing of pharmacological agents that are an integral part of the device under test.

醫療器材採認標準資料表

編號	DOH-000393
標準分類	F. 牙科裝置
標準號碼	ISO 3107:2004
標準名稱	Dentistry -- Zinc oxide/eugenol and zinc oxide/non-eugenol cements
制定日期	2006-03-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Dental cements
簡要說明	ISO 3107:2004 specifies the requirements and performance test methods for non-water-based zinc oxide/eugenol cements suitable for use in restorative dentistry for temporary cementation, for permanent cementation, for cavity liners and bases and as temporary restorations. ISO 3107:2004 is also applicable to non-eugenol cements containing zinc oxide and aromatic oils suitable for temporary cementation.

醫療器材採認標準資料表

編號	DOH-000394
標準分類	5. 材料
標準號碼	ISO 5832-5:2005
標準名稱	Implants for surgery -- Metallic materials -- Part 5: Wrought cobalt-chromium-tungsten-nickel alloy
制定日期	2005-10-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Wrought cobalt-chromium-tungsten-nickel alloy for use in the manufacture of surgical implants.
簡要說明	ISO 5832-5:2005 specifies the characteristics of, and corresponding test methods for, wrought cobalt-chromium-tungsten-nickel alloy for use in the manufacture of surgical implants. The tensile properties of a sample obtained from a finished product made of this alloy might not necessarily comply with those specified in ISO 5832-5:2005.

醫療器材採認標準資料表

編號	DOH-000395
標準分類	5. 材料
標準號碼	ISO 5834-2: 2006
標準名稱	Implants for surgery – Ultra-high molecular-weight polyethylene – Part 2: Moulded forms
制定日期	2006-04-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	IMPLANTABLE MEDICAL DEVICES
簡要說明	ISO 5834-2:2006 specifies the requirements and corresponding test methods for moulded forms (sheets, rods) made from ultra-high-molecular-weight polyethylene (UHMWPE) for use in the manufacture of surgical implants.

醫療器材採認標準資料表

編號	DOH-000396
標準分類	5. 材料
標準號碼	ISO 5834-3: 2005
標準名稱	Implants for surgery – Ultra-high molecular-weight polyethylene – Part 3: Accelerated ageing methods
制定日期	2005-07-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	IMPLANTABLE MEDICAL DEVICES
簡要說明	ISO 5834-3:2005 specifies a test method for investigating the oxidative stability of ultra-high-molecular-weight polyethylene (UHMWPE) materials as a function of processing and sterilization method. ISO 5834-3:2005 describes a laboratory method for accelerated ageing of UHMWPE specimens and components for total joint prostheses. The UHMWPE is aged at elevated temperature and at elevated oxygen pressure, to accelerate oxidation of the material and thereby allow for the evaluation of its potential long-term chemical and mechanical stability.

醫療器材採認標準資料表

編號	DOH-000397
標準分類	5. 材料
標準號碼	ISO 5834-4: 2005
標準名稱	Implants for surgery – Ultra-high molecular-weight polyethylene – Part 4: Oxidation index measurement method
制定日期	2005-05-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	IMPLANTABLE MEDICAL DEVICES
簡要說明	ISO 5834-4:2005 specifies a method for the measurement of the relative extent of oxidation present in ultra-high molecular weight polyethylene (UHMWPE). ISO 5834-4:2005 is applicable to ultra-high molecular weight polyethylene (UHMWPE) intended for use in medical implants.

醫療器材採認標準資料表

編號	DOH-000398
標準分類	5. 材料
標準號碼	ISO 5834-5: 2005
標準名稱	Implants for surgery – Ultra-high molecular-weight polyethylene – Part 5: Morphology assessment method
制定日期	2005-06-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Implantable Medical Devices
簡要說明	ISO 5834-5:2005 specifies the test method for assessing the morphology of UHMWPE moulded forms, which are described in ISO 5834-2. It is not applicable to UHMWPE powder forms, which are described in ISO 5834-1.

醫療器材採認標準資料表

編號	DOH-000399
標準分類	5. 材料
標準號碼	ISO 16428:2005
標準名稱	Implants for surgery – Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices
制定日期	2005-04-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	implantable materials and medical devices, Corrosion tests.
簡要說明	ISO 16428:2005 specifies standard environmental conditions for the testing of metallic materials intended for implantation, surgical implants, and medical devices. The testing conditions described simulate physiological conditions in a simplified manner controlling the test solution, the temperature, the gaseous atmosphere and the proportions of sample size and volume of solution. These environmental testing conditions can be employed where necessary in combination with various static or dynamic tests where the effect of the physiological environment is to be considered. Typical applications are corrosion fatigue tests and selected fretting and wear tests, as well as general electrochemical tests.

醫療器材採認標準資料表

編號	DOH-000400
標準分類	M. 骨科用裝置
標準號碼	ISO 14243-1: 2002
標準名稱	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
制定日期	2002-03-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Implants (surgical), Joints (anatomy), Knees, Prosthetic devices, Artificial joints, Prosthesis, Wear tests.
簡要說明	This part of ISO 14243 specifies the relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total knee-joint prostheses in wear-testing machines with load control.

醫療器材採認標準資料表

編號	DOH-000401
標準分類	M. 骨科用裝置
標準號碼	ISO 14243-2: 2000
標準名稱	Implants for surgery -- Wear of total knee-joint prostheses -- Part 2: Methods of measurement
制定日期	2000-10-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Implants (surgical), Joints (anatomy), Knees, Prosthetic devices, Artificial joints, Prosthesis, Wear tests, Mechanical testing.
簡要說明	This part of ISO 14243 specifies methods of assessment of wear of the tibial component of total knee-joint prostheses using gravimetric techniques and changes in dimensional form of components tested in accordance with ISO 14243-1.

醫療器材採認標準資料表

編號	DOH-000402
標準分類	M. 骨科用裝置
標準號碼	ISO 14243-3: 2004/Cor 1: 2006
標準名稱	Implants for surgery – Wear of total knee joint prostheses – Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test – Technical Corrigendum 1
制定日期	2006-02-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Surgery, Surgical equipment, Implants (surgical), Prosthetic devices, Prosthesis, Wear tests.
簡要說明	ISO 14243-3:2004 specifies relative movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total knee-joint prostheses in wear-testing machines having axial load control, flexion/extension angular motion control, AP displacement control and tibial rotation control. The kinematics of ISO 14243-3:2004 may not be applicable to knee designs with a high degree of constraint, which could result in damage to the articulating components in the early stages of the test that would not be representative of clinical service.

醫療器材採認標準資料表

編號	DOH-000403
標準分類	M. 骨科用裝置
標準號碼	ISO 14602:1998
標準名稱	Non-active surgical implants — Implants for Osteosynthesis — Particular requirements
制定日期	1998-05-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Implants (surgical), Orthopaedic equipment, Implants for Osteosynthesis.
簡要說明	This European standard specifies particular requirements for non-active surgical Implants for osteosynthesis, hereafter referred to as implants. In addition to EN ISO 14630:1997, this standard gives particular requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer.

醫療器材採認標準資料表

編號	DOH-000404
標準分類	M. 骨科用裝置
標準號碼	ISO 21535:2002
標準名稱	Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants
制定日期	2002-11-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Hip-joint replacement implants.
簡要說明	This International Standard provides specific requirements for hip-joint replacement implants. With regard to safety, this International Standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and methods of test.

醫療器材採認標準資料表

編號	DOH-000405
標準分類	D. 麻醉學用裝置
標準號碼	ISO 10524-1: 2006
標準名稱	Pressure regulators for use with medical gases – Part 1: Pressure regulators and pressure regulators with flow-metering devices
制定日期	2006-02-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Pressure regulators for use with medical gases
簡要說明	ISO 10524-1:2006 is applicable to the types of pressure regulators listed and is intended for the administration of the following medical gases in the treatment, management, diagnostic evaluation and care of patients: oxygen; nitrous oxide; air for breathing; helium; carbon dioxide; xenon; mixtures of the gases listed above; air for driving surgical tools; nitrogen for driving surgical tools. These pressure regulators are intended to be fitted to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and can be provided with devices which control and measure the flow of the medical gas delivered. The types of pressure regulators covered by ISO 10524-1:2006 are as follows: pressure regulators intended to be connected to cylinders by the operator; pressure regulators with integral flow-metering devices intended to be connected to cylinders by the operator; pressure regulators that are an integral part of medical equipment (e.g. anaesthetic workstations, lung ventilators, resuscitators).

醫療器材採認標準資料表

編號	DOH-000406
標準分類	D. 麻醉學用裝置
標準號碼	ISO 10524-2: 2005
標準名稱	Pressure regulators for use with medical gases – Part 2: Manifold and line pressure regulators
制定日期	2005-05-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Pressure regulators for use with medical gases
簡要說明	ISO 10524-2:2005 specifies requirements for manifold pressure regulators intended to be connected to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and for line pressure regulators for inlet pressures up to 3 000 kPa and intended for use in pipeline systems for the following medical gases: oxygen; nitrous oxide; air for breathing; carbon dioxide; oxygen/nitrous oxide mixtures; air for driving surgical tools; nitrogen for driving surgical tools; oxygen produced by an oxygen concentrator. ISO 10524-2:2005 applies to manifold pressure regulators and line pressure regulators supplied as individual units or to the relevant components incorporated within an assembly. It does not apply to pressure regulators for use with vacuum pipeline systems.

醫療器材採認標準資料表

編號	DOH-000407
標準分類	D. 麻醉學用裝置
標準號碼	ISO 10524-3: 2005
標準名稱	Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves
制定日期	2005-05-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Pressure regulators for use with medical gases
簡要說明	ISO 10524-3:2005 applies to pressure regulators integrated with cylinder valves intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients for use with the following medical gases: oxygen; nitrous oxide; air for breathing; helium; carbon dioxide; xenon; specified mixtures of the gases listed above; air for driving surgical tools; nitrogen for driving surgical tools. These pressure regulators integrated with cylinder valves are intended to be fitted to cylinders with nominal filling pressures up to 25 000 kPa at 15 °C and can be provided with devices that control and measure the flow of the medical gas delivered.

醫療器材採認標準資料表

編號	DOH-000408
標準分類	D. 麻醉學用裝置
標準號碼	ISO 10651-3: 1997
標準名稱	Lung ventilators for medical use -- Part 3: Particular requirements for emergency and transport ventilators
制定日期	1997-01-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Lung ventilators for medical use
簡要說明	Contains requirements for lung ventilators intended for the use in emergency situations and transport. These ventilators are often installed in ambulances or rescue vehicles. Based on IEC 601-1. The requirements of this part of ISO 10651 take precedence over those of IEC 601-1.

醫療器材採認標準資料表

編號	DOH-000409
標準分類	D. 麻醉學用裝置
標準號碼	ISO 10651-4: 2002
標準名稱	Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators
制定日期	2002-03-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Lung ventilators for medical use
簡要說明	Contains requirements for lung ventilators intended for the use in emergency situations and transport. These ventilators are often installed in ambulances or rescue vehicles. Based on IEC 601-1. The requirements of this part of ISO 10651 take precedence over those of IEC 601-1.

醫療器材採認標準資料表

編號	DOH-000410
標準分類	D. 麻醉學用裝置
標準號碼	ISO 10651-5: 2006
標準名稱	Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas powered emergency resuscitators
制定日期	2006-02-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Lung ventilators for medical use
簡要說明	ISO 10651-5:2006 specifies the basic safety and essential performance requirements for gas-powered emergency resuscitators intended for use with humans by first responders. This equipment is intended for emergency field use and is intended to be continuously operator attended in normal use. ISO 10651-5:2006 also specifies the requirements for resuscitator sets. ISO 10651-5:2006 is not applicable to electrically-powered resuscitators.

醫療器材採認標準資料表

編號	DOH-000411
標準分類	D. 麻醉學用裝置
標準號碼	ISO 21647: 2004/Cor 1:2005
標準名稱	Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors-Technical Corrigendum 1
制定日期	2005-07-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Medical breathing apparatus, respiratory gas monitors (RGM).
簡要說明	ISO 21647:2004 specifies particular requirements for the basic safety and essential performance of respiratory gas monitors (RGM) (as defined in 3.15) intended for continuous operation for use with humans. It supplements the requirements of IEC 60601-1:1988. ISO 21647:2004 specifies requirements for anaesthetic gas monitoring, carbon dioxide monitoring and oxygen monitoring.

醫療器材採認標準資料表

編號	DOH-000412
標準分類	P. 放射科學用裝置
標準號碼	IEC 61847: 1998
標準名稱	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics Ed. 1.0.
制定日期	1998-01-30
制定標準組織名稱	International Electrotechnical Commission
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Ultrasonic surgical systems operating in the 20 kHz to 60 kHz range and used for example in ophthalmology and neurology (e.g, phacoemulsifiers)
簡要說明	This standard specifies: - the essential non-thermal output characteristics of ultrasonic surgical units; - methods of measurement ot these output characteristics; - those characteristics which should be declared by the manufacturers of such equipment. This standard is applicable to equipment which meets the requirements of a, b and c below: a) ultrasonic surgical systems operating in the frequency range 20 kHz to 60 kHz; and b) ultrasonic surgical systems, whose use is the fragmentation or cutting of human tissue, whether or not those effects are delivered in conjunction with tissue removal or coagulation; and c) ultrasonic surgical systems, in which an acoustic wave is conducted by means of a specifically designed wave guide to deliver energy to the surgical site.

醫療器材採認標準資料表

編號	DOH-000413
標準分類	P. 放射科學用裝置
標準號碼	IEC 61689:1996
標準名稱	Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0.5 MHz to 5 MHz Ed. 1.0.
制定日期	1996-08-23
制定標準組織名稱	International Electrotechnical Commission
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Ultrasound deep heating therapy (diathermy type) devices
簡要說明	This standard specifies : - methods of measurement and characterization of the output performance of ultrasonic physiotherapy equipment based on reference testing methods; - characteristics to be declared by manufacturers of ultrasonic physiotherapy equipment based on reference testing methods; - requirements for performance and safety of the ultrasonic field generated by ultrasonic physiotherapy equipment; - methods of measurement and characterization of the output performance of ultrasonic physiotherapy equipment based on routine testing methods; - acceptance criteria for aspects of performance of ultrasonic physiotherapy equipment based on routine testing methods. Therapeutic value and methods of use of ultrasonic physiotherapy equipment are not covered by the scope of this standard. Cancels and replaces IEC 60150, published in 1963, and constitutes a technical revision.

醫療器材採認標準資料表

編號	DOH-000414
標準分類	P. 放射科學用裝置
標準號碼	ISO 11146-2:2005
標準名稱	Lasers and laser-related equipment - Test methods for laser beam widths, divergence angles and beam propagation ratios - Part 2: General astigmatic beams.
制定日期	2005-02-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment.
簡要說明	ISO 11146-2:2005 specifies methods for measuring beam widths (diameter), divergence angles and beam propagation ratios of laser beams. ISO 11146-2:2005 is applicable to general astigmatic beams or unknown types of beams. For stigmatic and simple astigmatic beams, ISO 11146-1 is applicable. Within ISO 11146-2:2005, the description of laser beams is accomplished by means of the second order moments of the Wigner distribution rather than physical quantities such as beam widths and divergence angles. However these physical quantities are closely related to the second order moments of the Wigner distribution. In ISO/TR 11146-3, formulae are given to calculate all relevant physical quantities from the measured second order moments.

醫療器材採認標準資料表

編號	DOH-000415
標準分類	P. 放射科學用裝置
標準號碼	ISO/TR 11146-3:2004/Cor 1:2005
標準名稱	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
制定日期	2005-02-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment
簡要說明	ISO/TR 11146-3:2004 specifies methods for measuring beam widths (diameter), divergence angles and beam propagation ratios of laser beams in support of ISO 11146-1. It provides the theoretical description of laser beam characterization based on the second-order moments of the Wigner distribution, including geometrical and intrinsic beam characterization, and offers important details for proper background subtraction methods recommendable for matrix detectors such as CCD cameras. It also presents alternative methods for the characterization of stigmatic or simple astigmatic beams that are applicable where matrix detectors are unavailable or deliver unsatisfying results.

醫療器材採認標準資料表

編號	DOH-000416
標準分類	P. 放射科學用裝置
標準號碼	IEC 60601-2-5:2000:
標準名稱	Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment Ed. 2.0.
制定日期	2000-7
制定標準組織名稱	International Electrotechnical Commission
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Ultrasound deep heating therapy (diathermy type) devices
簡要說明	This Particular Standard specifies requirements and tests for the safety of ultrasonic physiotherapy equipment. It amends and supplements IEC 60601-1 (second edition, 1988) including Amendments 1 and 2, hereinafter referred to as the General Standard. This Particular Standard takes into account IEC 60601-1-2 and IEC 61689.

醫療器材採認標準資料表

編號	DOH-000417
標準分類	P. 放射科學用裝置
標準號碼	ISO 9236-1:2004
標準名稱	Photography - Sensitometry of screen/film systems for medical radiography - Part 1: Determination of sensitometric curve shape, speed and average gradient.
制定日期	2004-02-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	X-Ray Film and Processing Equipment
簡要說明	ISO 9236-1:2004 specifies methods for the determination of the sensitometric curve shape, average gradient and speed of a single sample of a screen/film/filmholder/processing system for medical radiography. It is not applicable to special radiographic applications such as mammography, dental radiography and direct-exposing medical radiographic systems (see for example ISO 5799). The filmholder can be any means that ensures close screen/film contact and prevents the film from being exposed to ambient light. In particular, the filmholder can be a light-tight vacuum bag, as often used in the laboratory, or a radiographic cassette as used in medical radiography.

醫療器材採認標準資料表

編號	DOH-000418
標準分類	P. 放射科學用裝置
標準號碼	ISO 4090:2001
標準名稱	Photography - Medical radiographic cassette/screens/films and hard-copy imaging films - Dimensions and specifications.
制定日期	2001-08-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Radiographic Film and Any Device that Uses or Contains Film (e.g. Cassettes)
簡要說明	This International Standard specifies the nominal sizes, aim dimensions with tolerances, weights, and certain tests for medical radiographic cassettes, screens, and films. It includes medical hard-copy imaging films in the form of sheets, such as laser films and video. This International Standard also includes information regarding the appropriate marking of these products, and special attention is given to cassettes/screens/films used for mammography. This International Standard does not include films in roll format (see informative annex A).

醫療器材採認標準資料表

編號	DOH-000419
標準分類	P. 放射科學用裝置
標準號碼	ISO 5799:1991
標準名稱	Photography -- Direct-exposing medical and dental radiographic film/process systems -- Determination of ISO speed and ISO average gradient.
制定日期	1991-08-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	X-Ray Film and Processing Equipment
簡要說明	Specifies measuring methods so that the film/process system can be obtained reproducibly and can also be compared with those of other systems. Describes sensitometric procedures for films exposed directly to X-rays. This second edition cancels and replaces the first edition (1981).

醫療器材採認標準資料表

編號	DOH-000420
標準分類	P. 放射科學用裝置
標準號碼	IEEE N42.13-1986
標準名稱	Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides.
制定日期	1986
制定標準組織名稱	The Institute of Electrical and Electronics Engineers, Inc
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Radionuclide Dose Calibrators
簡要說明	This standard covers the technique for the quantification of the activity of identified radionuclides using any of a variety of ionization chambers currently available for this purpose. Application of the standard is limited to instruments that incorporate well-type ionization chambers as detectors. This standard provides a method for obtaining measurements that are accurate to within ±10% and reproducible to within ±5% [usually for sources of more than 100ţCI($3.7x10^6$ Bq)] The standard is also intended to assure continuing performance of the apparatus within these specifications. For purposes of this standard, accuracy andreproducibility are described in 4.6.

醫療器材採認標準資料表

編號	DOH-000421
標準分類	P. 放射科學用裝置
標準號碼	ISO 15367-1:2003
標準名稱	Lasers and laser-related equipment -- Test methods for determination of the shape of a laser beam wavefront -- Part 1: Terminology and fundamental aspects
制定日期	2003-09-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment.
簡要說明	ISO 15367-1:2003 specifies methods for the measurement of the topography of the wavefront of a laser beam by measurement and interpretation of the spatial distribution of the phase of that wavefront across a plane approximately perpendicular to its direction of propagation. Requirements are given for the measurement and analysis of phase distribution data to provide quantitative wavefront parameters and their uncertainty in a test report. The methods described in ISO 15367-1:2003 are applicable to the testing and characterization of a wide range of beam types from both continuous wave and pulsed lasers. Definitions of parameters describing wavefront deformations are given together with methods for the determination of those parameters from phase distribution measurements.

醫療器材採認標準資料表

編號	DOH-000422
標準分類	P. 放射科學用裝置
標準號碼	ISO 15367-2:2005
標準名稱	Lasers and laser-related equipment - Test methods for determination of the shape of a laser beam wavefront - Part 2: Shack-Hartman sensors.
制定日期	2005-03-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☑ Horizontal ☐ Vertical
影響產品或類別	Lasers and laser-related equipment.
簡要說明	ISO 15367-2:2005 specifies methods for measurement and evaluation of the wavefront distribution function in a transverse plane of a laser beam utilizing Hartmann or Shack-Hartmann wavefront sensors. ISO 15367-2:2005 is applicable to fully coherent, partially coherent and general astigmatic laser beams, both for pulsed and continuous operation. Furthermore, reliable numerical methods for both zonal and modal reconstruction of the two-dimensional wavefront distribution together with their uncertainty are described. The knowledge of the wavefront distribution enables the determination of several wavefront parameters that are defined in ISO 15367-1.

醫療器材採認標準資料表

編號	DOH-000423
標準分類	P. 放射科學用裝置
標準號碼	IEC 60825-1 - Consol. Ed. 1.2 (incl. am1+am2)
標準名稱	Safety of laser products - Part 1: Equipment classification, requirements and user's guide
制定日期	2001-08-30
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	Deals with the safety of laser products. Covers laser radiation in the wavelength range 180 nm to 1 mm, indicates safe working levels of laser radiation and introduces a system of classification of lasers and laser products according to their degree of hazard. Replaces IEC 60825 (1984) and IEC 60820 (1986). Has the status of a group safety publication in accordance with IEC Guide 104.

醫療器材採認標準資料表

編號	DOH-000424
標準分類	P. 放射科學用裝置
標準號碼	IEC 60825-2 - Ed. 3.0
標準名稱	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCS)
制定日期	2004-06
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	Provides requirements and specific guidance for the safe operation and maintenance of optical fibre communication systems (OFCS). In these systems optical power may be accessible outside the confinements of transmitting equipment or at great distance from the optical source. This Part 2 requires the assessment of hazard levels at accessible locations as a replacement for classification according to IEC 60825-1. It applies to the complete installed end-to-end OFCS, including its components and subassemblies that generate or amplify optical radiation. Individual components and subassemblies that are sold only to OEM vendors for incorporation into a complete installed end-to-end OFCS need not be assessed to this standard, since the final OFCS should itself be assessed according to this standard.

醫療器材採認標準資料表

編號	DOH-000425
標準分類	P. 放射科學用裝置
標準號碼	IEC/TR 60825-3 - Ed. 1.0
標準名稱	Safety of laser products - Part 3: Guidance for laser displays and shows
制定日期	1995-12-18
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	This publication is a code of practice for the design, installation, operation and evaluation of the safety of laser light shows and displays and the equipment employed in their production.

醫療器材採認標準資料表

編號	DOH-000426
標準分類	P. 放射科學用裝置
標準號碼	IEC 60825-4 - Consol. Ed. 1.2 (incl. am1+am2)
標準名稱	Safety of laser products - Part 4: Laser guards
制定日期	2003-10
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	Specifies the requirements for laser guards, permanent and temporary (for example for service), that enclose the process zone of a laser processing machine, and specifications for proprietary laser guards. This standard applies to all component parts of a guard including clear (visibly transmitting) screens and viewing windows, panels, laser curtains and walls. Requirements for beam path components, beam stops and those other parts of a protective housing of a laser product which do not enclose the process zone are contained in IEC 60825-1. In addition this part of IEC 60825 indicates: a) how to assess and specify the protective properties of a laser guard; and b) how to select a laser guard.

醫療器材採認標準資料表

編號	DOH-000427
標準分類	P. 放射科學用裝置
標準號碼	IEC/TR 60825-5 - Ed. 2.0
標準名稱	Safety of laser products - Part 5: Manufacturer's checklist for IEC 60825-1
制定日期	2003-06
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	This technical report is applicable to laser products as described in IEC 60825-1. The checklist is intended for use by manufacturers of laser products and their agents to establish that each new or modified design complies with the requirements of IEC 60825-1: 1993 and its amendments 1 and 2. The checklist is not a substitute for IEC 60825-1. It is necessary to use IEC 60825-1 in conjunction with the checklist, as relevant clauses and subclauses are referred to in the text.

醫療器材採認標準資料表

編號	DOH-000428
標準分類	P. 放射科學用裝置
標準號碼	IEC/TR 60825-8 - Ed. 1.0
標準名稱	Safety of laser products - Part 8: Guidelines for the safe use of medical laser equipment
制定日期	1999-11-25
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	Serves as a guide intended to give information to the employer and the user on the safe use of lasers and laser equipment classified as class 3B or class 4, for diagnostic and therapeutic applications in healthcare facilities. Explains the control measures recommended for the safety of patients, staff, maintenance personnel, and others. Engineering controls which form part of the laser equipment or the installation are also briefly described to provide an understanding of the general principles of protection.

醫療器材採認標準資料表

編號	DOH-000429
標準分類	P. 放射科學用裝置
標準號碼	IEC/TR 60825-9 - Ed. 1.0
標準名稱	Safety of laser products - Part 9: Compilation of maximum permissible exposure to incoherent optical radiation
制定日期	1999-10-29
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	Provides guidance for the protection of persons from incoherent optical radiation in the wavelength range from 180nm to 1 mm by indicating safe levels of optical radiation which are believed to be safe for most individuals in the sense that exposure at or below these levels will create no adverse effects.

醫療器材採認標準資料表

編號	DOH-000430
標準分類	P. 放射科學用裝置
標準號碼	IEC/TR 60825-10 - Ed. 1.0
標準名稱	Safety of laser products - Part 10: Application guidelines and explanatory notes to IEC 60825-1
制定日期	2002-02-22
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	This technical report gives information on the physics relating to the dangers posed by laser products. It complements, but does not replace, the information in IEC 60825-1 by explaining the underlying principles, so that the user may correctly interpret its requirements. The application of this technical report is limited to laser products with finite accessible emissions of laser radiation.

醫療器材採認標準資料表

編號	DOH-000431
標準分類	P. 放射科學用裝置
標準號碼	IEC/TR 60825-14 - Ed. 1.0
標準名稱	Safety of laser products - Part 14: A user's guide
制定日期	2004-02-25
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Optical radiation safety and laser equipment
簡要說明	This technical report provides guidance on best practice in the safe use of laser products that conform to IEC 60825-1. The terms 'laser product' and 'laser equipment' as used in this document also refer to any device, assembly or system, which is capable of emitting optical radiation produced by a process of stimulated emission. However, unlike IEC 60825-1, this document does not cover light-emitting diodes (LEDs). Class 1 laser products normally pose no hazard and Class 2 laser products present only a minimal hazard. With these products, it is normally sufficient to follow the warnings on the product labels and the manufacturer's instructions for safe use. Further protective measures as described in this document should not be necessary. This document emphasizes evaluation of the risk from higher power lasers, but the users of the lower power lasers may benefit from the information contained. This technical report can be applied to the use of any product that incorporates a laser, whether or not it is sold or offered for sale. Therefore, it applies to specially constructed lasers (including experimental and prototype systems). This technical report is intended to help laser users and their employers to understand the general principles of safety management (Clause 3), to identify the hazards that may be present (Clauses 4 to 6), to assess the risks of harm that may arise (Clause 7), and to set up and maintain appropriate control measures (Clauses 8 to 11). Reference is made in this document to laser 'users'. This should be taken to include persons having responsibility for safety in addition to those who actually work with or operate laser equipment.

醫療器材採認標準資料表

編號	DOH-000432
標準分類	1. 通用
標準號碼	ISO/TR 16142
標準名稱	Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices
制定日期	2006-01-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	All medical devices.
簡要說明	ISO/TR 16142:2006 considers and identifies certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance. ISO/TR 16142:2006 is intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes.

醫療器材採認標準資料表

編號	DOH-000433
標準分類	1. 通用
標準號碼	IEC 60601-1-8:2003/Amd 1:2006
標準名稱	Medical electrical equipment -- Part 1-8: General requirements for safety -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
制定日期	2006-03-08
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Alarm systems in medical electrical equipment and medical electrical systems
簡要說明	This collateral standard specifies requirements for ALARM SYSTEMS and ALARM SIGNALS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. It also provides guidance for the application of ALARM SYSTEMS.

醫療器材採認標準資料表

編號	DOH-000434
標準分類	1. 通用
標準號碼	IEC 60601-1:2005
標準名稱	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
制定日期	2005-12-15
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	All electrical medical equipments
簡要說明	Contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. For certain types of medical electrical equipment, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

醫療器材採認標準資料表

編號	DOH-000435
標準分類	1. 通用
標準號碼	IEC 60601-1-2: 2005 Consol. Ed. 2.1 (incl. am1)
標準名稱	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
制定日期	2004-11
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	All electrical medical equipments
簡要說明	Specifies requirements and tests for electromagnetic compatibility of equipment and systems and serves as the basis of electromagnetic compatibility requirements and tests in Particular Standards (60601-2-series). The existence of electromagnetic emission standards is essential for the protection of: - safety services; - other equipment and systems; - non-medical electrical equipment (e.g. computers); - telecommunications (e.g. radio/TV, telephone, radio-navigation). The existence of electromagnetic immunity requirements is essential to assure safety of equipment and systems. The immunity test levels specified in this standard (IEC 60601 test levels) represent the range found in the general medical use environment.

醫療器材採認標準資料表

編號	DOH-000436
標準分類	1. 通用
標準號碼	IEC 60812: 2006 - Ed. 2.0
標準名稱	Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)
制定日期	2006-01-25
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	All medical devices
簡要說明	This International Standard describes Failure Mode and Effects Analysis (FMEA) and Failure Mode, Effects and Criticality Analysis (FMECA), and gives guidance as to how they may be applied to achieve various objectives by: providing the procedural steps necessary to perform analysis; identifying appropriate terms; defining basic principles; providing examples of the necessary worksheets or other tabular forms.

醫療器材採認標準資料表

編號	DOH-000437
標準分類	1. 通用
標準號碼	ISO 14971:2000/ Amd 1:2003
標準名稱	Medical devices -- Application of risk management to medical devices
制定日期	2003-03-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	All medical devices
簡要說明	As explained in the Introduction, a risk management standard applying to all medical devices is required. Risks exist throughout the product life cycle, and risks that become apparent at one point in the life cycle may be managed by action taken at a completely different point in the life cycle. For this reason, this International Standard is intended to be a complete life cycle standard. This means that it instructs manufacturers to apply risk management principles to a medical device from its initial conception until its ultimate decommissioning and disposal.

醫療器材採認標準資料表

編號	DOH-000438
標準分類	4. 軟體
標準號碼	IEC 62304:2006 - Ed. 1.0
標準名稱	Medical device software - Software life cycle processes
制定日期	2006-05-09
制定標準組織名稱	International Electrotechnical Commission (IEC)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Medical device software
簡要說明	Defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes. Applies to the development and maintenance of medical device software when software is itself a medical device or when software is an embedded or integral part of the final medical device. This standard does not cover validation and final release of the medical device, even when the medical device consists entirely of software.

醫療器材採認標準資料表

編號	DOH-000439
標準分類	1. 通用
標準號碼	CNS14991
標準名稱	命名—用於醫療器材法規管理資料交換之命名系統的規格
制定日期	2006-06-01
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	醫療器材資料庫
簡要說明	依此命名系統建立資料庫。 在本標準中包含適用於發展與維護醫療器材辨識之命名分類規定。 備考1.本標準不包含分類，分類將於另一份文件中。 2.用於補充醫療器材指令之特定規定

醫療器材採認標準資料表

編號	DOH-000440
標準分類	1. 通用
標準號碼	CNS14989
標準名稱	醫療器材風險管理
制定日期	2006/06/01
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	所有醫療器材
簡要說明	本標準規範製造商為識別醫療器材及其附件包括體外診斷用的醫療器材在內危害性之程序、估計及評估風險、控制這些風險和監控的有效性。 本標準可應用於醫療器材生命週期中所有階段，但不適用於使用醫療器材時之臨床判斷。 本標準並不規範可接受的風險等級，亦不要求製造商有正式的品質系統存在。然而，風險管理可以整合為品質系統的一部份。

醫療器材採認標準資料表

編號	DOH-000441
標準分類	1. 通用
標準號碼	CNS14990
標準名稱	醫療器材—用於醫療器材標識、標示與資訊之符號
制定日期	2006/06/01
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	所有醫療器材
簡要說明	本標準鑑別習慣上使用的符號，這些符號對維護使用者與其他人之安全與有效使用醫療器材分享。本標準主要預定使用於： -於許多國家市場銷售產品需使用不同語言醫療器材標示的醫療器材製造商； -購自許多來源及具備多種語言能力以提供醫療器材的使用者； -負責上市後監督者； -健康照顧之管理機構、驗證機構、認證體系以及其他可能對醫療器材產生影響之立法權責機構與負責上市後監視機構。

醫療器材採認標準資料表

編號	DOH-000442
標準分類	1. 通用
標準號碼	CNS15013
標準名稱	用於法規目的之醫療器材品質管理系統要求
制定日期	2006/06/13
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	醫療器材品質管理系統
簡要說明	本標準規定品質管理系統之要求，以供從事醫療器材之設計、開發、生產、安裝與服務之組織，以及醫療器材相關服務之設計、開發與供應組織使用。 本標準提供內部與外部機構包括查證機構，用以評估組織符合顧客與法規要求之能力。

醫療器材採認標準資料表

編號	DOH-000443
標準分類	4. 軟體
標準號碼	AAMI TIR32:2004
標準名稱	Medical device software risk management
制定日期	2004/12/23
制定標準組織名稱	The Association for the Advancement of Medical Instrumentation
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Medical device software
簡要說明	This AAMI technical information report provides information useful to performing effective software risk management, a significant part of the overall risk management process for medical devices containing software. It does this in the context of ANSI/AAMI/ISO 14971:2000, Medical devices— Application of risk management to medical devices, and in the context of ANSI/AAMI SW68:2001, Medical device software—Software life cycle processes.

醫療器材採認標準資料表

編號	DOH-000444
標準分類	4. 軟體
標準號碼	ANSI/AAMI SW68:2001
標準名稱	Medical device software—Software life cycle processes
制定日期	2001/06/05
制定標準組織名稱	AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)/ The Association for the Advancement of Medical Instrumentation(AAMI)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	All medical devices containing software
簡要說明	Defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes, with well-defined terminology that can be referenced by the medical device software industry.

醫療器材採認標準資料表

編號	DOH-000445
標準分類	D. 麻醉學用裝置
標準號碼	EN ISO 18779:2005
標準名稱	Medical devices for conserving oxygen and oxygen mixtures - Particular requirements
制定日期	2005-02-15
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Medical breathing apparatus, conserving oxygen and oxygen mixtures.
簡要說明	ISO 18779:2005 specifies requirements for the safety and essential performance of portable devices that supply the flow of oxygen or oxygen mixtures during therapy (e.g. long term oxygen therapy, analgesia). These devices are intended to conserve oxygen or oxygen mixtures by delivering these gases intermittently on the patient's demand when used in home care applications. These devices are generally used without continual professional supervision. These devices are also used in health care facilities/institutions.

醫療器材採認標準資料表

編號	DOH-000446
標準分類	E. 心臟血管用裝置
標準號碼	AAMI/ANSI/ISO 5840:2005
標準名稱	Cardiovascular implants - Cardiac valve prostheses
制定日期	2005-03-07
制定標準組織名稱	ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI)/ AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)/ INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Cardiac valve prostheses
簡要說明	The standard is applicable to all devices intended for implantation in human hearts, as a heart valve substitute. It is applicable to both newly developed and modified heart valve substitutes and to the accessory devices, packaging and labelling required for their implantation and for determining the appropriate size of heart valve substitute to be implanted.

醫療器材採認標準資料表

編號	DOH-000447
標準分類	E. 心臟血管用裝置
標準號碼	ISO 14708-2: 2005
標準名稱	Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers
制定日期	2005-10-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Cardiac pacemakers
簡要說明	ISO 14708-2:2005 specifies requirements that are applicable to those active implantable medical devices intended to treat bradyarrhythmias (cardiac pacemakers). The tests that are specified in ISO 14708-2:2005 are type tests, and are to be carried out on samples of a device to show compliance. ISO 14708-2:2005 is also applicable to some non-implantable parts and accessories of the devices. The device that is commonly referred to as an active implantable medical device may in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

醫療器材採認標準資料表

編號	DOH-000448
標準分類	E. 心臟血管用裝置
標準號碼	ISO 25539-1: 2003/Amd 1: 2005
標準名稱	Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses – Amendment 1: Test methods
制定日期	2005-07-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Endovascular prostheses
簡要說明	ISO 25539-1:2003 specifies requirements for endovascular prostheses, based upon current medical knowledge. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization packaging and information supplied by the manufacturer. It should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants. ISO 25539-1:2003 is applicable to endovascular prostheses used to treat arterial aneurysms, arterial stenoses, or other appropriate vascular abnormalities. ISO 25539-1:2003 is applicable to delivery systems if they comprise an integral component of the deployment of the endovascular prostheses.

醫療器材採認標準資料表

編號	DOH-000449
標準分類	E. 心臟血管用裝置
標準號碼	ISO 15676:2005
標準名稱	Cardiovascular implants and artificial organs – Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)
制定日期	2005-07-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)
簡要說明	ISO 15676:2005 specifies requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO). ISO 15676:2005 is applicable to all medical tubing intended for cardiopulmonary bypass (CPB) and/or extracorporeal membrane oxygenation (ECMO), but specific requirements and tests are included for tubing intended for use with peristaltic pumps during (short-term, i.e. < 6 h duration) CPB surgery, or (long-term, i.e. > 24 h) ECMO procedures. The sterility and non-pyrogenicity provisions of ISO 15676:2005 are applicable to tubing packs labelled as "sterile". ISO 15676:2005 is applicable only to the tubing aspects for multifunctional systems that may have integral components such as blood gas exchangers (oxygenators), reservoirs, blood filters, defoamers, blood pumps, etc.

醫療器材採認標準資料表

編號	DOH-000450
標準分類	E. 心臟血管用裝置
標準號碼	ISO 7198:1998
標準名稱	Cardiovascular implants — Tubular vascular prostheses
制定日期	1998-08-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Tubular vascular prostheses
簡要說明	This International Standard specifies requirements relating to testing, packaging, labelling and terminology for sterile tubular vascular prostheses intended to replace, bypass or to form shunts between segments of the vascular system in humans. This International Standard addresses vascular prostheses that are made wholly or partly of: materials of biological origin; synthetic textile materials; and synthetic nontextile materials. In addition, guidance for characterization of compound and composite prostheses is provided. It specifies the designation of materials of manufacture and the construction, and specifies the designation of sizes and dimensions of vascular prostheses. It refers to biological requirements of the materials of construction and of the finished product, taking into account the appropriate part of the horizontal International Standard ISO 10993.

醫療器材採認標準資料表

編號	DOH-000451
標準分類	E. 心臟血管用裝置
標準號碼	ISO 7199:1996
標準名稱	Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)
制定日期	1996-12-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Blood-gas exchangers (oxygenators)
簡要說明	Requirements for sterile, single-use, extracorporeale blood-gas exchangers (oxygenators) intended for supply of oxygen to, and removal of carbon dioxide from, the blood of humans.

醫療器材採認標準資料表

編號	DOH-000452
標準分類	E. 心臟血管用裝置
標準號碼	ISO 8637:2004
標準名稱	Haemodialysers, haemofilters and haemoconcentrators
制定日期	2004-10-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Haemodialysers, haemofilters and haemoconcentrators
簡要說明	haemofilters and haemoconcentrators, hereinafter collectively referred to as 'the device', for use for humans. ISO 8637:2004 is not applicable to extracorporeal blood circuits, plasmafilters, haemoperfusion devices, vascular access devices, blood pumps, pressure monitors for the extracorporeal blood circuit, air detection devices, systems to prepare, maintain or monitor dialysate, systems used to perform haemofiltration or haemoconcentration, reprocessing procedures and equipment. Requirements for the extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters are specified in ISO 8638.

醫療器材採認標準資料表

編號	DOH-000453
標準分類	E. 心臟血管用裝置
標準號碼	ISO 8638:2004
標準名稱	Extracorporeal blood circuit for haemodialysers, haemofilters and haemoconcentrators
制定日期	2004-10-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Haemodialysers, haemofilters and haemoconcentrators
簡要說明	ISO 8638:2004 specifies requirements for single-use extracorporeal blood circuits (hereafter referred to as "the device") and (integral and non-integral) transducer protectors which are intended for use in haemodialysis, haemodiafiltration and haemofiltration. ISO 8638:2004 is not applicable to haemodialysers, haemodiafilters or haemofilters, plasmafilters, haemoperfusion devices, vascular access devices, blood pumps, pressure monitors for the extracorporeal blood circuit, air detection devices, systems to prepare, maintain or monitor dialysing fluid, or systems intended to perform haemofiltration or haemoconcentration.

醫療器材採認標準資料表

編號	DOH-000454
標準分類	E. 心臟血管用裝置
標準號碼	ISO 15674:2001
標準名稱	Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags
制定日期	2001-11-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	sterile, single-use, extracorporeal hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags.
簡要說明	This International Standard specifies requirements for sterile, single-use, extracorporeal hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags intended for use as a blood reservoir during cardiopulmonary bypass (CPB) surgery. This International Standard applies only to the blood reservoir aspects for multifunctional systems which may have integral components such as blood-gas exchangers (oxygenators), blood filters, defoamers, blood pumps, etc.

醫療器材採認標準資料表

編號	DOH-000455
標準分類	E. 心臟血管用裝置
標準號碼	ISO 15675:2001
標準名稱	Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial line blood filters
制定日期	2001-10-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Sterile, single-use, arterial filters intended to filter and remove emboli, debris, blood clots and other potentially hazardous solid and gaseous material
簡要說明	This International Standard specifies requirements for sterile, single-use, arterial filters intended to filter and remove emboli, debris, blood clots and other potentially hazardous solid and gaseous material from the blood of humans during cardiopulmonary bypass surgery.

醫療器材採認標準資料表

編號	DOH-000456
標準分類	E. 心臟血管用裝置
標準號碼	ISO 13960:2003
標準名稱	Cardiovascular implants and artificial organs – Plasmafilters
制定日期	2003-12-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Plasmafilters
簡要說明	ISO 13960:2003 specifies requirements for sterile, single-use plasmafilters, intended for use on humans. ISO 13960:2003 is not applicable to the extracorporeal circuits used for plasmapheresis or other extracorporeal blood exchange devices, such as haemodialysers, haemodiafilters, haemofilters, haemoperfusion devices, vascular access devices, oxygenators or active medical devices. ISO 13960:2003 does not address the replacement fluid.

醫療器材採認標準資料表

編號	DOH-000457
標準分類	I. 一般整形及外科手術裝置
標準號碼	D6978-05
標準名稱	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
制定日期	2005
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Medical gloves (examination and surgeon's gloves)
簡要說明	This practice covers a protocol for the assessment of resistance of medical glove materials to permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact. An assessment is made based on the permeation (breakthrough) of nine chemotherapy drugs through the glove material over a certain period of time. It is emphasized that the conditions used in this assessment are intended to approximate the worst-case condition for clinical uses. The data should be restricted to use on a relative basis when comparing glove materials.

醫療器材採認標準資料表

編號	DOH-000458
標準分類	I. 一般整形及外科手術裝置
標準號碼	ISO 7886-3:2005
標準名稱	Sterile hypodermic syringes for single use -- Part 3: Auto-disable syringes for fixed-dose immunizatio
制定日期	2005-03-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Anti-stick syringe; Piston syringe; Hypodermic single-lumen needles
簡要說明	ISO 7886-3:2005 specifies the properties and performance of sterile single-use hypodermic syringes with or without needle, made of plastic materials and stainless steel and intended for the aspiration of vaccines or for the injection of vaccines immediately after filling. Upon delivering a fixed dose of vaccine the syringe is automatically rendered unusable.

醫療器材採認標準資料表

編號	DOH-000459
標準分類	I. 一般整形及外科手術裝置
標準號碼	D7160-05
標準名稱	Standard Practice for Determination of Expiration Dating for Medical Gloves
制定日期	2005
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Surgical and Examination Gloves
簡要說明	This practice covers all surgeon's and examination gloves made from either synthetic or natural rubber latex. The purpose of this practice is to establish methods for testing medical gloves and analyzing the data to determine their shelf life. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

醫療器材採認標準資料表

編號	DOH-000460
標準分類	I. 一般整形及外科手術裝置
標準號碼	D7161-05
標準名稱	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions
制定日期	2005
制定標準組織名稱	ASTM International
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Surgical and Examination Gloves that have been manufactured for at least one year prior to the publication of ASTM D7160.
簡要說明	This practice covers all surgeon's and examination gloves, made from either synthetic or natural rubber latex, marketed at the time this practice is published, for which there is no previous real time aging data available, and for which there are at least 12 months of storage as finished goods under typical warehouse conditions. This practice describes how to develop real time aging data for gloves that are part of finished goods inventory (including gloves that may no longer be manufactured) in order to verify the estimated expiration date (see Note 1). Manufacturers may use this data as a starting point for real time aging studies as described in Practice D 7160.

醫療器材採認標準資料表

編號	DOH-000461
標準分類	M. 眼科用裝置
標準號碼	Z80.7-2002
標準名稱	Ophthalmics - Intraocular Lenses
制定日期	2002.
制定標準組織名稱	AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Intraocular Lenses
簡要說明	Applies to the Physical & Mechanical Requirements, Optical Requirements, & Biocompatibility and Chemical Testing Requirements of Intraocular Lenses.

醫療器材採認標準資料表

編號	DOH-000462
標準分類	M. 眼科用裝置
標準號碼	Z80.20-2004
標準名稱	Ophthalmics -- Contact lenses -- Standard Terminology, Tolerances, Measurements and Physicochemical Properties.
制定日期	2004.
制定標準組織名稱	AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
標準型態	☐ Horizontal ☑ Vertical
影響產品或類別	Contact Lenses
簡要說明	This American National Standard applies to contact lenses which are devices worn over the front surface of the eye in contact with the preocular tear film. The standard covers rigid (hard) intracorneal and haptic (scleral) contact lenses, as well as flexible paralimbal contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers, and fluorosiloxanes, etc. Flexible lenses are easily deformable and may require support for proper shape. A very large subset of flexible lenses are so-called "soft" (hydrophilic) contact lenses, which are made of transparent hydrogels containing water in concentrations greater than or equal to 10%. Flexible lenses can also be made of non-hydrogel materials, e.g., flexible polysiloxanes (silicone elastomers).

醫療器材採認標準資料表

編號	DOH-000463
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 11608-4:2006
標準名稱	Pen-injectors for medical use – Part 4:Requirements and test methods for electronic and electromechanical pen-injectors
制定日期	2006-03-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Pen-injectors
簡要說明	ISO 11608-4:2006 specifies requirements and test methods for electromechanically driven injectors intended to be used with needles and with replaceable or non-replaceable cartridges. The injector may be for single-use or multiple-use. The injector system is intended to deliver medication to an end-user by self-administration or with assistance.

醫療器材採認標準資料表

編號	DOH-000464
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 21649:2006
標準名稱	Needle-free injectors for medical use –Requirements and test methods
制定日期	2006-06-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Injection instruments.
簡要說明	ISO 21649:2006 applies to safety and performance and testing requirements for single-use and multiple-use needle-free injection systems intended for human use in clinics and other medical settings and for personal use by patients. The dose chamber of the injection system is often disposable and intended to be replaced after either a single use or a limited number of uses. It is sometimes separable from the injection mechanism and often termed a "cartridge", "ampoule", "syringe", "capsule" or "disc". In contrast, the dose chamber also may be a permanent internal chamber designed to last through the claimed life of the device.

醫療器材採認標準資料表

編號	DOH-000465
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8362-1:2003
標準名稱	Injection containers and accessories -- Part 1: Injection vials made of glass tubing
制定日期	2003-09-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Injection instruments, Injection vials.
簡要說明	ISO 8362-1:2003 specifies the form, dimensions and capacities of glass vials for injectable preparations. It also specifies the material from which such containers shall be made and the performance requirements of those containers. ISO 8362-1:2003 applies to colourless or amber glass containers made from borosilicate or soda-lime glass, in the form of glass tubing, whether internally surface-treated or not, and intended for use in the packaging, storage or transportation of products intended for injection.

醫療器材採認標準資料表

編號	DOH-000466
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8362-2:1988
標準名稱	Injection containers for injectables and accessories -- Part 2: Closures for injection vials
制定日期	1988- 12- 15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Injection instruments, Phials, Injection containers, injection vials
簡要說明	Specifies the design, dimensions, material, performance, requirements and tests for single-use closures for injection vials covered by ISO 8362-1 and ISO 8362-4. The three normative annexes contain test methods for the penetrability by means of a needle and the subsequent self-healing of the closures.

醫療器材採認標準資料表

編號	DOH-000467
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8362-3:2001
標準名稱	Injection containers and accessories -- Part 3: Aluminium caps for injection vials
制定日期	2001-12-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Injection instruments, aluminium caps for injection vials.
簡要說明	This part of ISO 8362 specifies aluminium caps for injection vials as described in ISO 8362-1 and ISO 8362-4.

醫療器材採認標準資料表

編號	DOH-000468
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8362-4:2003
標準名稱	Injection containers and accessories -- Part 4: Injection vials made of moulded glass
制定日期	2003-08-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Injection instruments, Injection vials.
簡要說明	ISO 8362-4:2003 specifies the shape, dimensions and capacities of glass vials for injectable preparations. It also specifies the material from which such containers shall be made and the performance requirements for the containers. It applies to colourless or amber glass containers moulded from borosilicate or soda-lime glass, with or without an internal surface treatment, and intended to be used in the packaging, storage or transportation of products intended for injection.

醫療器材採認標準資料表

編號	DOH-000469
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8362-5:1995
標準名稱	Injection containers for injectables and accessories -- Part 5: Freeze drying closures for injection vials
制定日期	1995-l 2-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Freeze drying closures for injection vials
簡要說明	Describes the design, dimensions, materials, performance and test for the type of closure for injection vials, as described in ISO 8362-1 and ISO 8362-4, which is used at the freeze drying (or lyophilization) of drugs and biological materials

醫療器材採認標準資料表

編號	DOH-000470
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8362-6:1992
標準名稱	Injection containers for injectables and accessories -- Part 6: Caps made of aluminium-plastics combinations for injection vials
制定日期	1992-10-01
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Caps made of aluminium-plastics combinations for injection vials
簡要說明	Specifies classification of types, dimensions and tolerances, designation, requirements, packaging, and marking.

醫療器材採認標準資料表

編號	DOH-000471
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8362-7:2006
標準名稱	Injection containers and accessories –Part 7: Injection caps made of aluminiumplastics combinations without overlapping plastics part
制定日期	2006-04-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Injection caps made of aluminiumplastics combinations without overlapping plastics part
簡要說明	ISO 8362-7:2006 specifies aluminium-plastics combinations for the injection caps of injection vials, as specified in ISO 8362-1 and ISO 8362-4, where the plastics part does not overlap the diameter of the vial body.

醫療器材採認標準資料表

編號	DOH-000472
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 8536-1:2006
標準名稱	Infusion equipment for medical use -- Part 1: Infusion glass bottles
制定日期	2006-03-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Parenteral infusion equipment, Infusion glass bottles.
簡要說明	ISO 8536-1:2006 specifies the dimensions, performance and requirements of infusion glass bottles necessary to ensure functional interchangeability. It is applicable only to infusion bottles for single use.

醫療器材採認標準資料表

編號	DOH-000473
標準分類	J. 一般醫院及個人使用裝置
標準號碼	ISO 9187-1:2006
標準名稱	Injection equipment for medical use –Part 1: Ampoules for injectables
制定日期	2006-04-15
制定標準組織名稱	International Organization for Standardization (ISO)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Injection instruments, Ampoules for injectables.
簡要說明	ISO 9187-1:2006 specifies materials, dimensions, capacities, performance and packaging requirements for three forms of glass ampoule (forms B, C and D) for injectable pharmaceutical products. It is applicable to ampoules with and without a colour break-ring. The provision of ampoules with a colour break-ring, and the choice of colour of the break-ring, is subject to agreement between the manufacturer and user. Ampoules complying with ISO 9187-1:2006 are intended for single use only.

醫療器材採認標準資料表

編號	DOH-000474
標準分類	E. 心臟血管用裝置
標準號碼	EN 14299:2004
標準名稱	Non active surgical implants - Particular requirements for cardiac and vascular implants - Specific requirements for arterial stents
制定日期	2004/06/08
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	cardiac and vascular implants, arterial stents
簡要說明	This European Standard specifies specific requirements for arterial stents and their deployment intended to correct or compensate a defect of an artery. With regard to safety, this standard gives in addition to EN ISO 14630 and EN 12006-3 specific requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer. This European Standard applies to arterial stents for Aorta, Coronary arteries, Pulmonary arteries, Visceral arteries, Supra-aortic arteries, cervical segments of Cerebral arteries and Intra-cerebral arteries. It also includes Peripheral arteries, including endovascular prosthesis used to treat aneurysm or arterial stenosis.

醫療器材採認標準資料表

編號	DOH-000475
標準分類	E. 心臟血管用裝置
標準號碼	EN 12006-1:1999
標準名稱	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 1: Heart valve substitutes
制定日期	1999/11/15
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Cardiac and vascular implants, Heart valve substitutes
簡要說明	The document specifies particular requirements for heart valve substitutes. It is not applicable to heart valve substitutes comprised in whole, or in part, of human tissue. With regard to safety, it gives requirements for intended performance characteristics of equipment to be used to determine the physical, biological and chemical properties of heart valve substitutes and of the material and components of which they are made. Recommendations are also made for in vivo testing and clinical evaluation, and for the reporting of results of all types of testing and evaluation covered in the document. These recommendations do not purport to comprise a complete test program

醫療器材採認標準資料表

編號	DOH-000476
標準分類	E. 心臟血管用裝置
標準號碼	EN 12006-2:1998
標準名稱	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits
制定日期	1998/07/15
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Cardiac and vascular implants, Vascular prostheses including cardiac valve conduits
簡要說明	The document specifies particular requirements for vascular prostheses and cardiovascular patches of synthetic or biological origin intended to replace, reconstruct, bypass or to form shunts between segments for the cardio-vascular system in humans.

醫療器材採認標準資料表

編號	DOH-000477
標準分類	E. 心臟血管用裝置
標準號碼	EN 12006-3:1998
標準名稱	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices
制定日期	1999/03/15
制定標準組織名稱	European Committee for Standardization (CEN)
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	Cardiac and vascular implants, Endovascular devices
簡要說明	The document specifies particular requirements for endovascular devices. With regard to safety, this document gives in addition to prEN ISO 14630, requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

醫療器材採認標準資料表

編號	DOH-000478
標準分類	J. 一般醫院及個人使用裝置
標準號碼	CNS 4397
標準名稱	脫脂紗布
制定日期	2005-10
制定標準組織名稱	經濟部標準檢驗局
標準型態	☐ Horizontal ☐ Vertical
影響產品或類別	脫脂紗布
簡要說明	本標準適用於脫脂紗布之品質、試驗條件、式樣及試片之採取與準備、檢驗、標示。備考：醫療用脫脂紗布除應符合本標準之規定外，亦應符合衛生主管機關之相關規定。