附件 2、歷年廢除之原採認醫療器材標準清單

說明:

1. 本清單所列醫療器材標準，為本署過去曾公告採認，然該項標準已被廢除者。
2. 提供 104 年至 114 年廢除之醫療器材標準共 264 項如下表。

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

					medical services environment
10.	1 Anesthesias 麻醉學	ISO	ISO 21647: 2004/Cor 1:2005	2005	Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors-Technical Corrigendum 1
11.	1 Anesthesias 麻醉學	ISO	ISO 18779:2005	2005	Medical devices for conserving oxygen and oxygen mixtures - Particular requirements
12.	1 Anesthesias 麻醉學	CNS	CNS 15003-1	2006	醫療氣體管線系統－第１部：壓縮醫療氣體及真空用管線
13.	1 Anesthesias 麻醉學	CNS	CNS 15003-2	2006	醫療氣體管線系統－第２部：麻醉氣體之清理排放系統
14.	1 Anesthesias 麻醉學	CNS	CNS 15005-1	2006	醫療氣體管線系統之終端單元－第１部：壓縮醫療氣體與真空用終端單元
15.	1 Anesthesias 麻醉學	CNS	CNS 15005-2	2006	醫療氣體管線系統之終端單元－第２部：麻醉氣體清理系統之終端單元
16.	1 Anesthesias 麻醉學	ASTM	ASTM F1850-00/(R)2005	2005	Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components
17.	1 Anesthesias 麻醉學	EN	EN 13544-1:2007+A1:2009	2010	Respiratory therapy equipment - Part 1: Nebulizing systems and their components - Incorporates Amendment A1: 2009
18.	1 Anesthesias 麻醉學	IEC	IEC 60601-2-13:2009	2009	Medical electrical equipment – Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems - Edition 3.1; Consolidated Reprint
19.	1 Anesthesias 麻醉學	ISO	ISO 8359:1996/Amd 1:2012	2012	Oxygen Concentrators for Medical Use - Safety Requirements
20.	2 Biocompatibility 生物相容性	ISO	ISO/TS 20993:2006	2006	Biological evaluation of medical devices -- Guidance on a risk-management process

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

	臟血管醫學				requirements
32.	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F2065-00e1/(R)2010	2010	Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials
33.	3 Cardiovascular 心臟血管醫學	CEN	EN 1060-3:1997+A2:2009	2009	Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems
34.	3 Cardiovascular 心臟血管醫學	CEN	EN 12006-2:1998+A1:2009	2009	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2:Vascular prostheses including cardiac valve conduits
35.	3 Cardiovascular 心臟血管醫學	CNS	CNS 14509-2-49	2014	醫電設備－第 2-49 部:多功能患者監視設備安全之個別規定 Medical electrical equipment－Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IDT: IEC 61267:2005)
36.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13294:1997	1997	Dental Handpieces - Dental Air-Motors
37.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7494:1996	1996	Dental Units
38.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7785-1:1997	1997	Part 1: High-Speed Air Turbine Handpieces
39.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 7785-2:1995	1995	Part 2: Straight and Geared Angle Handpieces
40.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 1562:1993	1993	Dental Casting Gold Alloys
41.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 1563:1990	1990	Dental Alginate Impression Material

42.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 1564:1995	1995	Dental Aqueous Impression Materials Based on Agar
43.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6871-1:1994	1994	Dental base metal casting alloys Part 1: Cobalt-based alloys - TECHNICAL CORRIGENDUM 1:1998
44.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 6871-2:1994	1994	Dental Base Metal Casting Alloys Part 2: Nickel-Based Alloys
45.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 11498:1997	1997	Dental Handpieces: Dental Low Voltage Electrical Motors
46.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13294:1997	1997	Dental Handpieces - Dental Air-Motors
47.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 8891:2000	1998	Dental Casting Alloys with Noble Metal Content of At Least 25% but less than 75%
48.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 13716:1999	1999	Dentistry - Reversible-Irreversible Hydrocolloid Impression Material Systems
49.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9693:1999/Amd 1:2005	2005	Metal-ceramic dental restorative systems.
50.	4 Dental/ENT 牙科學/耳鼻喉科學	CNS	CNS 14496	2012	牙科材料-牙用聚合材料顏色穩定性的測定 (Dental materials-Determination of color stability of dental polymeric aterials)
51.	4 Dental/ENT 牙科學/耳鼻喉科學	ISO	ISO 9693-1:2012	2012	Dentistry — Compatibility testing — Part 1: Metal-ceramic systems - First Edition
52.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 14155-1	2003	Clinical investigation of medical devices for human subjects — Part 1: General requirements
53.	5 General I (QS/RM)	ISO	ISO 14155-2	2003	Clinical investigation of medical devices for human subjects — Part 2:

	通用(品質管理系統/風險管理)				Clinical investigation plans
54.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO/TR 16142	2006	Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices
55.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS15013	2006	用於法規目的之醫療器材品質管理系統要求
56.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	IEC 62366:2007	2007	Medical devices - Application of usability engineering to medical devices
57.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS 14509-1-6	2015	醫電設備－第 1-6 部：基本安全與必要性能之一般要求－附屬標準:可用性(Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability)
58.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO/TS 19218-1/Amd1:2013	2013	Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes AMENDMENT 1 - First Edition
59.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	AAMI TIR36:2007	2007	Validation of software for regulated processes
60.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院	ISO	ISO 595/1	1988	Reusable all-glass or metal-and-glass syringes for medical use - Part 1: Dimensions

	及個人使用裝置				
61.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 595/2	1987	Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements and tests
62.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F882-84(R2002)	1985	Standard Performance and Safety Specification for Cryosurgical Medical Instruments
63.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F2196-02	2002	Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices
64.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14509	2012	醫電設備電性安全－第 1 部：一般安全規定 Medical Electrical Equipment--Part 1: General Requirements for Safety (IDE IEC 60601-1:1988)
65.	6 General Plastic Surgery/General Hospital 一般及整形	CNS	CNS 14509-1	2013	醫電設備電性安全－第一部分：一般安全規定－附屬標準 1：醫電系統之安全規定 Medical Electrical Equipment--Part 1-1: General Requirements for Safety-Collateral Standard: Safety Requirements for

	外科手術/一般醫院及個人使用裝置				Medical Electrical systems (IDE IEC 60601-1-1)
66.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14509-2	2013	醫電設備電性安全－第一部分：一般安全規定－附屬標準 2：電磁相容性之規定與測試 Medical Electrical Equipment--Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility-Requirements and Tests (IDE IEC 60601-1-2)
67.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14509-4	2013	醫電設備電性安全－第一部分：一般安全規定－附屬標準 4：可程式化醫電系統 Medical Electrical Equipment--Part 1-4: General Requirements for Safety-Collateral Standard: Programmable Electrical Medical Systems (IDE IEC 60601-1-4)
68.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14624-1	2002	醫療用輸液設備－第一部分：玻璃點滴瓶
69.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14624-4	2002	醫療用輸液設備—第四部份：單次使用之重力式輸液套
70.	6 General Plastic Surgery/General	CNS	CNS 14624-5	2002	醫療用輸液設備—第五部份：量管型輸液套

	Hospital 一般及整形外科手術/一般醫院及個人使用裝置				
71.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14624-6	2002	醫療用輸液設備一第六部份：點滴瓶之凍晶乾燥瓶塞
72.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14624-7	2002	醫療用輸液設備一第七部份：鋁一塑膠組合成之點滴瓶蓋
73.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-38:1996/Amd.1:1999	1999	Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds
74.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 594-1:1986	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
75.	6 General Plastic	ISO	ISO 594-2:1998	1998	Conical fittings with a 6% (Luer) taper for syringes, needles and certain

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				other medical equipment - Part 2: Lock fittings
76.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	AAMI	II36:2004	2004	Medical electrical equipment - Part 2: Particular requirements for safety of baby incubators
77.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CEN	EN 12470-5:2003	2003	Clinical thermometers —Part 5: Performance of infra-red ear thermometers (with maximum device)
78.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CEN	EN 12470-3:2000	2000	Clinical thermometers —Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device
79.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	AAMI	ANSI/AAMI BF7:2012	2012	Blood transfusion micro-filters

80.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CEN	EN 13795:2011+A1:2013	2013	Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels
81.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14509-2-59	2014	醫電設備－第 2-59 部:人體發燒體溫篩檢熱影像儀之基本安全與必要性能之個別規定 Medical electrical equipment Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IDT: IEC 80601-2-59:2008)
82.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CEN	EN 13726-1	2003	Test methods for primary wound dressings - Part 1: Aspects of absorbency
83.	7 In Vitro Diagnostics 體外診斷醫療器材	CEN	EN 13640:2002	2002	Stability Testing of In Vitro Diagnostic Reagents
84.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS GP 10-A:1995	1995	Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline
85.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS GP19-A2:2001	2003	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition
86.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS NRSCL 8-A:1998	1998	Terminology and Definitions for use in NCCLS Documents; Approved Standard

87.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C12-A	1994	Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard (1994)
88.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C21-A	1992	Performance Characteristics for Devices Measuring PO2 and PCO2 in Blood Samples; Approved Standard (1992)
89.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C25-A	1997	Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline (1997)
90.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C27-A	1993	Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline (1993)
91.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C42-A	1996	Erythrocyte Protoporphyrin Testing; Approved Guideline (1996)
92.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H10-A2	1995	Solubility Test to Confirm the Presence of Sickling Hemoglobins - Second Edition; Approved Standard (1995)
93.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H14-A2	1990	Devices for Collection of Skin Puncture Blood Specimens - Second Edition; Approved Guideline (1990)
94.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA6-A	1997	Detection and Quantitation of Rubella IGG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline (1997)
95.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA10-A	1996	Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline (1996)
96.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA17-A	1997	Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Neural Tube Defects; Approved Guideline (1997)

97.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA19-A	1997	Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (1997)
98.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	DI1-A2	1992	Glossary and Guidelines for Immunodiagnostic Procedures, Reagents and Reference Materials-Second Edition
99.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C29-A2	2000	Standardization of Sodium and Potassium Ion Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard (2000)
100.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C31-A2	2001	Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline - Second Edition (2001)
101.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	DI02-A2	1993	Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials - Second Edition; Approved Guideline
102.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H07-A3	2000	Procedure for Determining Packed Cell Volume by the Microhematocrit Method - Second Edition; Approved Standard - Third Edition
103.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H30-A2	2001	Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline Second Edition
104.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H51-A	2002	Assays of vonWillebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline
105.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	LA01-A2	1994	Assessing the Quality of Radioimmunoassay Systems - Second Edition; Approved Guideline
106.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	RS2-A	1998	The National Reference System for the Clinical Laboratory (NRSCL) Aspartate Aminotransferase (AST)
107.	7 In Vitro Diagnostics	CLSI	RS3-A	1987	The National Reference System for the Clinical Laboratory (NRSCL)

	體外診斷醫療器材				Cholesterol
108.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	RS5-A2	1993	The National Reference System for the Clinical Laboratory (NRSCL) Total Protein
109.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	RS6-A	1989	The National Reference System for the Clinical Laboratory (NRSCL) Total Bilirubin
110.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	T/DM6-A	1997	Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997)
111.	7 In Vitro Diagnostics 體外診斷醫療器材	CEN	EN 375:2001	2000	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
112.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA23-A	2004	Assessing the Quality of Immunoassay Systems: Radioimmunoassays, and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guidelines
113.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO/TR 18112:2006	2006	Clinical laboratory testing and in vitro diagnostic test systems─In vitro diagnostic medical devices for professional use─Summary of regulatory requirements for information supplied by the manufacturer
114.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C3-A4	2006	Preparation and Testing of Reagent Water in the Clinical Laboratory
115.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM12-A	2006	Diagnostic nucleic acid microarrays
116.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C38-A	1997	Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline
117.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H17-A	1998	Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard
118.	7 In Vitro Diagnostics	CLSI	MM4-A	1999	Quality Assurance for Immunocytochemistry; Approved Guideline

	體外診斷醫療器材				
119.	7 In Vitro Diagnostics 體外診斷醫療器材	CNS	CNS 15035:2006	1996	體外診斷系統－糖尿病管理時自我檢測用血糖監測系統之規定
120.	7 In Vitro Diagnostics 體外診斷醫療器材	ANSI	AST3-A	1999	Wellness Testing Using IVD Devices; Approved Guideline
121.	7 In Vitro Diagnostics 體外診斷醫療器材	ANSI	AST4-A2	2005	Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition
122.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP10-A	1995	Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline
123.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M21-A	1999	Methodology for the Serum Bactericidal Test; Approved Guideline
124.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M31-S1	2004	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Informational Supplement
125.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M31-A2	2002	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard—Second Edition
126.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M32-P	2001	Evaluation of Lots of Dehydrated Mueller-Hinton Broth for Antimicrobial Susceptibility Testing; Proposed Guideline
127.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M6-A2	2006	Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard - Second Edition
128.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	ILA2-A2	2006	Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods; Approved Guideline - Second Edition

129.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP27-A2	2007	Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline - Second Edition
130.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP20-A2	2003	Fine-Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline-Second Edition
131.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H49-A	2004	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline
132.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C30-A2	2002	Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities
133.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C28-A3	2008	How to Define and Determine Reference Intervals in the Clinical Laboratory
134.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	EP09-A2-IR	2010	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition (Interim Revision)
135.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM02-A2	2002	Immunoglobin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline - Second Edition
136.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H04-A6	2008	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Sixth Edition
137.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	POCT02-A	2008	Implementation Guide of POCT01 for Health Care Providers; Approved Guideline
138.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M31-A3	2008	Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard - Third Edition
139.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA30-A	2008	Immunoassay Interference by Endogenous Antibodies; Approved Guideline
140.	7 In Vitro Diagnostics	CLSI	MM16-A	2006	Use of External RNA Controls in Gene Expression Assays; Approved

	體外診斷醫療器材				Guideline
141.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP22-A3	2011	Quality Management System: Continual Improvement; Approved Guideline—Third Edition
142.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	AUTO13-A2	2003	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition; Vol. 23; No. 4
143.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	NCCLS GP14-A	1996	Labeling of Home-Use In Vitro Testing Products; Approved Guideline
144.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	C44-A	2002	Harmonization of Glycohemoglobin Measurements; Approved Guideline
145.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	H45-A2	2005	Performance of the Bleeding Time Test; Approved Guideline
146.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA29-A	2008	Detection of HLA-Specific Alloantibody by Flow Cytometry and Solid Phase Assays; Approved Guideline
147.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	I/LA18-A2	2001	Specifications for Immunological Testing for Infectious Diseases; Approved Guideline - Second Edition
148.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	GP16-A3	2009	Urinalysis; Approved Guideline - Third Edition
149.	8 Materials 材料	ISO	ISO 5832-8:1997	1997	Implants for surgery -- Metallic materials -- Part 8: Wrought cobalt-nickel-chromium-molybdenum- tungsten-iron alloy
150.	8 Materials 材料	CNS	CNS 13382-18	1995	外科植入物–生物相容性–材料及器材之生物檢測方法的選擇（準則）
151.	8 Materials 材料	CNS	CNS 13382-24	1996	外科植入物–超高分子量聚乙烯（第一部分：粉狀）
152.	8 Materials 材料	CNS	CNS 13382-25	1996	外科植入物–超高分子量聚乙烯（第二部分：成形材）

153.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD5:2003	2007	Hemodialysis systems
154.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD16:2007	2007	Cardiovascular implants and artificial organs - Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators
155.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD17:2007	2007	Cardiovascular implants and artificial organs - Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters
156.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD52:2004	2004	Dialysate for hemodialysis
157.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD61:2006	2007	Concentrates for hemodialysis
158.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD62:2006	2007	Water treatment equipment for hemodialysis applications

159.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8638:2010	2010	Cardiovascular implants and extracorporeal systems -- Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters
160.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	RD5:2003/(R)2008	2008	Hemodialysis systems
161.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	RD52:2004/(R)2010 (incl A1 through A4)	2010	Dialysate for hemodialysis (consolidated text with Amendments 1 through 4 included)
162.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 13959:2014	2014	Water for haemodialysis and related therapies - Third Edition
163.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 26722:2014	2014	Water treatment equipment for haemodialysis applications and related therapies - Second Edition
164.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI 23500:2014	2014	Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

165.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	CEN	EN 1283:1996	1996	Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits
166.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8637:2010/Amd 1:2013	2013	Revision to Figure 2 -- Main fitting dimensions of dialysis fluid inlet and outlet ports
167.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	EN	EN 1618:1997	1997	Catheters Other than Intravascular Catheters - Test Methods for Common Properties
168.	10 Ophthalmic 眼科學	ISO	ISO 10338:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of curvature
169.	10 Ophthalmic 眼科學	ISO	ISO 10339:1997	1997	Ophthalmic optics -- Contact lenses -- Determination of water content of hydrogel lenses
170.	10 Ophthalmic 眼科學	ISO	ISO 10340:1995	1995	Optics and optical instruments -- Contact lenses -- Method for determining the extractable substances
171.	10 Ophthalmic 眼科學	ISO	ISO 10344:1996	1996	Optics and optical instruments -- Contact lenses -- Saline solution for contact lens testing
172.	10 Ophthalmic 眼科學	ISO	ISO 9913-1:1996	1996	Optics and optical instruments -- Contact lenses -- Part 1: Determination of oxygen permeability and transmissibility with the FATT method
173.	10 Ophthalmic 眼科學	ISO	ISO 9913-2:2000	2000	Optics and optical instruments -- Contact lenses -- Part 2: Determination of oxygen permeability and transmissibility by the coulometric method

174.	10 Ophthalmic 眼科學	ISO	ISO 8321-1:2002	2002	Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 1: Rigid corneal and scleral contact lenses
175.	10 Ophthalmic 眼科學	ISO	ISO 8321-2:2000	2000	Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 2: Single-vision hydrogel contact lenses
176.	10 Ophthalmic 眼科學	ISO	ISO 8599:1994	1994	Optics and optical instruments -- Contact lenses -- Determination of the spectral and luminous transmittance
177.	10 Ophthalmic 眼科學	ISO	ISO 9337-1:1999	1999	Contact lenses -- Determination of back vertex power -- Part 1: Method using focimeter with manual focusing
178.	10 Ophthalmic 眼科學	ISO	ISO 9338:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of the diameters
179.	10 Ophthalmic 眼科學	ISO	ISO 9339-1:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of the thickness -- Part 1: Rigid contact lenses
180.	10 Ophthalmic 眼科學	ISO	ISO 9339-2:1998	2000	Optics and optical instruments -- Contact lenses -- Determination of thickness -- Part 2: Hydrogel contact lenses
181.	10 Ophthalmic 眼科學	ISO	ISO 9340:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of strains for rigid contact lenses
182.	10 Ophthalmic 眼科學	ISO	ISO 9341:1996	1996	Optics and optical instruments -- Contact lenses -- Determination of inclusions and surface imperfections for rigid contact lenses
183.	10 Ophthalmic 眼科學	ISO	ISO 9914:1995	1995	Optics and optical instruments -- Contact lenses -- Determination of refractive index of contact lens materials
184.	10 Ophthalmic 眼科學	ANSI	ANSI Z80.20-2010	2010	Ophthalmics - Contact Lenses - Standard Terminology, Tolerances, Measurements and Physicochemcial Properties

185.	10 Ophthalmic 眼科學	ISO	ISO 11979-9:2006/Amd 1:2014	2014	Ophthalmic implants - Intraocular lenses - Part 9: Multifocal intraocular lenses AMENDMENT 1 - First Edition
186.	11 Orthopaedics 骨科學	CNS	CNS 13382-9	1995	外科植入物–骨髓內釘系統（第二部分：骨髓釘）
187.	11 Orthopaedics 骨科學	CNS	CNS 13382-10	1995	外科植入物–骨科人工關節–基本需求
188.	11 Orthopaedics 骨科學	CNS	CNS 13382-11	1995	外科植入物–半人工及全人工膝關節（第一部分：分類、定義及尺寸之標示）
189.	11 Orthopaedics 骨科學	CNS	CNS 13382-12	1995	外科植入物–金屬骨螺絲具有六角螺絲頭螺絲之起子接觸帽孔，球形之螺帽下表面，不對稱之螺紋–尺寸
190.	11 Orthopaedics 骨科學	CNS	CNS 13382-13	1995	外科植入物–具錐形下表面螺絲頭之金屬骨螺絲–尺寸
191.	11 Orthopaedics 骨科學	CNS	CNS 13382-14	1995	外科植入物–聚甲基丙烯酸甲脂　第一部分: 骨科應用
192.	11 Orthopaedics 骨科學	CNS	CNS 13382-15	1995	外科植入物–金屬骨板–螺絲孔適用不對稱螺紋及球形下表面之螺絲
193.	11 Orthopaedics 骨科學	CNS	CNS 13382-16	1995	外科植入物–金屬骨板–螺絲孔及槽適用於錐形下表面螺絲
194.	11 Orthopaedics 骨科學	CNS	CNS 13382-17	1995	外科植入物–骨髓內釘系統–第一部分：橫斷面為梅花狀或Ⅴ型之骨髓內釘
195.	11 Orthopaedics 骨科學	CNS	CNS 13382-19	1995	外科植入物–骨板彎曲強度與勁度的測定
196.	11 Orthopaedics 骨科	CNS	CNS 13382-20	1995	外科植入物–半及全人工髖關節–第一部分：分類、尺寸標示及規定

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197.	11 Orthopaedics 骨科學	CNS	CNS 13382-21	1995	外科植入物–半及全人工髖關節–第二部分：由金屬及塑膠製成之軸承面
198.	11 Orthopaedics 骨科學	CNS	CNS 13382-22	1995	外科植入物–半及全人工髖關節–第三部分：不含扭力之股骨柄耐久性測試
199.	11 Orthopaedics 骨科學	CNS	CNS 13382-23	1995	外科植入物–半及全人工髖關節–第四部分：含扭力之股骨柄耐久性測試
200.	11 Orthopaedics 骨科學	CNS	CNS 13382-26	1996	外科植入物–骨針及骨線（第一部分：材料與機械特性要求）
201.	11 Orthopaedics 骨科學	CNS	CNS 13382-27	1996	外科植入物–骨針及骨線(第二部分:Ｓｔｅｉｎｍａｎｎ骨針–尺度)
202.	11 Orthopaedics 骨科學	CNS	CNS 13382-28	1996	外科植入物–骨科使用之平行腳Ｕ形釘（一般要求）
203.	11 Orthopaedics 骨科學	CNS	CNS 13382-29	1996	外科植入物–不對稱螺紋與球形底面之金屬骨螺釘（機械要求及測試方法）
204.	11 Orthopaedics 骨科學	CNS	CNS 13382-30	1996	外科植入物–成人之股骨端固定用裝置
205.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-23	2007	輪椅－第 23 部：介護者操作爬梯裝置之要求與測試方法
206.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-24	2007	輪椅－第 24 部：使用者操作爬梯裝置之要求與測試方法
207.	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO4-A	2001	Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard

208.	13 Software/Informatics 軟體/醫療資訊	AAMI	ANSI/AAMI SW68:2001	2001	Medical device software—Software life cycle processes
209.	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO1-A	2000	Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard
210.	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO5-A	2001	Laboratory Automation: Electromechanical Interfaces; Approved Standard
211.	13 Software/Informatics 軟體/醫療資訊	CLSI	AUTO7-A	2004	Laboratory Automation: Data Content for Specimen Identification; Approved Standard
212.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 1074-2006	2006	IEEE Standard for Developing a Software Project Life Cycle Process
213.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232	1998	醫療資訊通信協定第七層
214.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI SW87:2012	2012	Application of quality management system concepts to medical device data systems
215.	14 Radiology 放射學科學	IEC	IEC 60601-2-32:1994	1994	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Associated Equipment of X-ray Equipment (1994)
216.	14 Radiology 放射學	IEC	IEC 60601-2-9:1996	1997	Medical electrical equipment - Part 2: Particular requirements for the

	科學				safety of patient contact dosimeters used in radiotherapy with electrically connected radiation detectors - Ed. 2.0
217.	14 Radiology 放射學科學	ISO	ISO 11810-1:2005	2005	Optics and optical Instruments - Lasers and laser-related equipment - Test method for the laser-resistance of surgical drapes and/or patient-protective covers
218.	14 Radiology 放射學科學	ISO	ISO 11146:1999	2005	Lasers and laser-related equipment - Test methods for laser beam parameters - Beam widths, divergence angle and beam propagation factor
219.	14 Radiology 放射學科學	ISO	ISO 11254-1:2000	2000	Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 1: 1-on-1 test
220.	14 Radiology 放射學科學	ISO	ISO 11254-2:2001	2001	Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 2: S-on-1 test
221.	14 Radiology 放射學科學	CNS	CNS 14509-3	2001	Medical Electrical Equipment--Part 1-3: General Requirements for Safety-Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment (IDE IEC 60601-1-3)
222.	14 Radiology 放射學科學	IEC	IEC/TR 60825-5:2003 Ed. 2.0	2003	Safety of laser products - Part 5: Manufacturer's checklist for IEC 60825-1
223.	14 Radiology 放射學科學	IEC	IEC/TR 60825-9 - Ed. 1.0	1999	Safety of laser products - Part 9: Compilation of maximum permissible exposure to incoherent optical radiation
224.	14 Radiology 放射學科學	IEC	IEC/TR 60825-10 - Ed. 1.0	2002	Safety of laser products - Part 10: Application guidelines and explanatory notes to IEC 60825-1
225.	14 Radiology 放射學科學	CNS	CNS 14176-1	2005	醫學數位影像及通信－第 1 部：簡介與概述
226.	14 Radiology 放射學	CNS	CNS 14176-2	2005	醫學數位影像及通信－第 2 部：符合性

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227.	14 Radiology 放射學科學	CNS	CNS 14176-3	1998	醫學數位影像及通信－第 3 部：資訊物件定義
228.	14 Radiology 放射學科學	CNS	CNS 14176-4	1998	醫學數位影像及通信－第 4 部：服務類別規格
229.	14 Radiology 放射學科學	CNS	CNS 14176-5	1998	醫學數位影像及通信－第 5 部：資料結構及編碼
230.	14 Radiology 放射學科學	CNS	CNS 14176-6	2005	醫學數位影像及通信－第 6 部：資料辭典
231.	14 Radiology 放射學科學	CNS	CNS 14176-7	1998	醫學數位影像及通信－第 7 部：訊息交換
232.	14 Radiology 放射學科學	CNS	CNS 14176-8	2005	醫學數位影像及通信－第 8 部：訊息交換之網路通信支援
233.	14 Radiology 放射學科學	CNS	CNS 14176-9	1998	醫學數位影像及通信－第 9 部：訊息交換之點對點通信支援
234.	14 Radiology 放射學科學	CNS	CNS 14176-10	2007	醫學數位影像及通信－第 10 部：媒體交換之媒體儲存與檔案格式
235.	14 Radiology 放射學科學	CNS	CNS 14176-11	2007	醫學數位影像及通信－第 11 部：媒體儲存應用規範
236.	14 Radiology 放射學科學	CNS	CNS 14176-12	2007	醫學數位影像及通信－第 12 部：媒體交換之媒體格式與實體媒體
237.	14 Radiology 放射學科學	CNS	CNS 14176-14	2007	醫學數位影像及通信－第 14 部：灰階標準顯示函數
238.	14 Radiology 放射學	CNS	CNS 14176-15	2007	醫學數位影像及通信－第 15 部：安全規範

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239.	14 Radiology 放射學科學	CNS	CNS 14176-18	2008	醫學數位影像及通信－第 18 部：DICOM 永續物件之資訊網存取
240.	14 Radiology 放射學科學	CNS	CNS 15585	2013	醫電設備電性安全－X 射線診斷造影使用之游離腔及/或半導體偵檢器劑量計 (Medical electrical equipment − Dosimeter with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging (IDT: IEC 61674:1997))
241.	14 Radiology 放射學科學	IEC	IEC 61223-2-6:2006	2006	Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment - Edition 2.0
242.	14 Radiology 放射學科學	CNS	CNS 14509-2-28	2014	醫電設備－ 第 2-28 部： 醫用診斷 X 射線管組件基本安全及必要性能之特殊要求(Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis)
243.	14 Radiology 放射學科學	IEC	IEC 60601-2-26:2015	2015	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
244.	14 Radiology 放射學科學	IEC	IEC 61223-3-5:2004+Corr1:2006	2006	Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment - Edition 1.0
245.	15 Sterility 滅菌	ISO	ISO 11134：1994	1994	Sterilization of health care products - Requirements for validation and routine control-industrial moist heat sterilization.
246.	15 Sterility 滅菌	ISO	ISO 11135：1994	1994	Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.
247.	15 Sterility 滅菌	ISO	ISO 11137：1995,	2001	Sterilization of Health Care Products - Requirements for Validation and

			Amendment 1：2001		Routine Control-Radiation Sterilization and Amendment 1
248.	15 Sterility 滅菌	ISO	ISO 11607:2000	2003	Packaging for terminally sterilized medical devices
249.	15 Sterility 滅菌	CNS	CNS 14709	2013	Sterilization of medical devices - Validation and routine control of sterilisation by irradiation (MOD ISO 11737)
250.	15 Sterility 滅菌	AAMI	ST66:1999	1999	Sterilization of health care products Chemical indicators Part 2: Class 2 indicators for air removal test sheets and packs
251.	15 Sterility 滅菌	ISO	ISO 11135-1:2007	2007	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
252.	15 Sterility 滅菌	ISO	ISO/TS 11135-2:2008	2008	Sterilization of health care products -- Ethylene oxide -- Part 2: Guidance on the application of ISO 11135-1
253.	15 Sterility 滅菌	ISO	ISO 17665-1	2006	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
254.	15 Sterility 滅菌	ISO	ISO/TS 17665-2	2009	Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1
255.	16 Tissue Engineering 組織工程	ASTM	ASTM F2311-08	2008	Standard Guide for Classification of Therapeutic Skin Substitutes
256.	16 Tissue Engineering 組織工程	ASTM	ASTM F2451-05/(R)2010	2010	Standard Guide for in vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage
257.	17 Neurology 神經學	ASTM	ASTM F1542-94 (R2000)	1994	Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips
258.	17 Neurology 神經學	CNS	CNS 14509-2-10	2014	醫電設備－第 2-10 部：神經與肌肉刺激器基本安全及必要性能之特殊要求(Medical electrical equipment – Part 2-10: Particular requirements

					for the basic safety and essential performance of nerve and muscle stimulators)
259.	17 Neurology 神經學	AAMI	AAMI NS28:1988/(R)2015	2015	Intracranial Pressure Monitoring Devices
260.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-1：2000	2000	Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems.
261.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-4：2000	2000	Medical Electrical Equipment - Part 1: General requirements for safety; 4. Collateral Standard: Programmable electrical medical systems.
262.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-2-22:2012	2012	Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment - Edition 3.1
263.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ISO	ISO/TS 19218-2:2012	2012	Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes - First Edition
264.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F2119-07(2013)	2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants