衛生福利部食品藥物管理署醫療器材標準採認資料

附件 1、109 年度醫療器材採認標準總清單(1,000 項)。

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

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

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

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

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

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

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

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

86	2 Biocompatibility 生物相容性	TFDA-01780	ISO	ISO 18562-2:2017	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter	原採認標準
87	2 Biocompatibility 生物相容性	TFDA-01781	ISO	ISO 18562-3:2017	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)	原採認標準
88	2 Biocompatibility 生物相容性	TFDA-01782	ISO	ISO 18562-4:2017	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate	原採認標準
89	2 Biocompatibility 生物相容性	TFDA-01875	ASTM	ASTM F2382 - 18	2018	Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)	原採認標準
90	2 Biocompatibility 生物相容性	TFDA-01937	ISO	ISO 10993-1:2018	2018	Biological evaluation of medical devices -- Part 1:Evaluation and testing within a risk management process	109 年度新增採認標準
91	2 Biocompatibility 生物相容性	TFDA-01938	ASTM	ASTM F2148-18	2018	Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	109 年度新增採認標準
92	2 Biocompatibility 生物相容性	TFDA-01939	ISO	ISO 10993-15:2019	2019	Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals an	109 年度新增採認標準
93	2 Biocompatibility 生物相容性	TFDA-01940	ISO	ISO 10993-18:2020	2020	Biological evaluation of medical devices —Part 18: Chemical characterization of materials	109 年度新增採認標準
94	2 Biocompatibility 生物相容性	TFDA-01941	ISO	ISO/TS 10993-19:2020	2020	Biological evaluation of medical devices —Part 19: Physico-chemical, morphological and topographical characterization of materials	109 年度新增採認標準
95	2 Biocompatibility 生物相容性	TFDA-01942	ISO	ISO 10993-9:2019	2019	Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products	109 年度新增採認標準
96	2 Biocompatibility 生物相容性	TFDA-01943	ASTM	ASTM F719 - 20	2020	Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	109 年度新增採認標準

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

362	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00319	CEN	EN 13612:2002	2002	Performance evaluation of in vitro diagnostic medical devices	原採認標準
363	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00321	ISO	ISO 18153:2003	2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials	原採認標準
364	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00324	CLSI	I/LA23-A	2004	Assessing the Quality of Immunoassay Systems: Radioimmunoassays, and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guidelines	原採認標準
365	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00328	CLSI	H56-A	2006	Body fluid analysis for cellular composition	原採認標準
366	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00329	CLSI	I/LA02-A2	2006	Quality assurance of laboratory tests for autoantibodies to nuclear antigens: (1)Indirect fluorescence assay for microscopy and (2) Microtiter enzyme immunoassay methods	原採認標準
367	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00332	CLSI	MM12-A	2006	Diagnostic nucleic acid microarrays	原採認標準
368	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00333	CLSI	C38-A	1997	Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline	原採認標準
369	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00334	CLSI	C39-A	2000	A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard	原採認標準
370	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00336	CLSI	C44-A	2002	Harmonization of Glycohemoglobin Measurements; Approved Guideline	原採認標準
371	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00337	CLSI	C45-A	2004	Measurement of Free Thyroid Hormones; - Approved Guideline	原採認標準

372	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00339	CLSI	H45-A2	2005	Performance of the Bleeding Time Test; Approved Guideline	原採認標準
373	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00481	CLSI	POCT01-A2	2006	Point-of-Care Connectivity; Approved Standard- Second Edition	原採認標準
374	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00494	CLSI	C37-A	1999	Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline	原採認標準
375	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00496	CLSI	EP06-A	2003	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline	原採認標準
376	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00506	CLSI	M26-A	1999	Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline	原採認標準
377	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00512	CLSI	MM13-A	2006	Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline	原採認標準
378	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00646	CLSI	H21-A5	2008	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - Fifth Edition	原採認標準
379	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00647	CLSI	I/LA21-A2	2008	Clinical Evaluation of Immunoassays; Approved Guideline-Second Edition	原採認標準
380	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00651	CLSI	H20-A2	2007	Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition	原採認標準
381	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00652	CLSI	H42-A2	2007	Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline - Second Edition	原採認標準
382	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00653	CLSI	H43-A2	2007	Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline - Second Edition	原採認標準

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

394	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00851	CLSI	C43-A2	2010	Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline-Second Edition	原採認標準
395	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00853	CLSI	POCT02-A	2008	Implementation Guide of POCT01 for Health Care Providers; Approved Guideline	原採認標準
396	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00941	CLSI	H54-A	2005	Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline	原採認標準
397	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00942	CLSI	H57-A	2008	Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline	原採認標準
398	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00943	CLSI	I/LA29-A	2008	Detection of HLA-Specific Alloantibody by Flow Cytometry and Solid Phase Assays; Approved Guideline	原採認標準
399	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00944	CLSI	I/LA30-A	2008	Immunoassay Interference by Endogenous Antibodies; Approved Guideline	原採認標準
400	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-00945	CLSI	EP25-A	2009	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline	原採認標準
401	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01107	CLSI	C61-A	1998	Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard	原採認標準
402	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01108	CLSI	C40-A2	2013	Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline	原採認標準
403	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01109	CLSI	EP17-A2	2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition	原採認標準
404	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01110	CLSI	GP40-A4-AMD	2012	Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline, Fourth Edition	原採認標準
405	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01111	CLSI	GP42-A6	2008	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard--Sixth Edition	原採認標準

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

417	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01131	CLSI	POCT12-A3	2013	Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline, Third Edition,	原採認標準
418	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01133	CLSI	POCT14-A	2004	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline	原採認標準
419	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01134	CLSI	QMS06-A3	2011	Quality Management System: Continual Improvement; Approved Guideline - Third Edition; Vol 31; No 14	原採認標準
420	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01137	CNS	CNS 15449-2-101	2014	量測、控制及實驗室使用電氣設備安全規定－第 2-101 部:體外診斷(IVD)醫用設備之個別規定 Safe requirements for electrical for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IDT: IEC 61010-2-101:2002)	原採認標準
421	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01138	CLSI	GP34-A	2010	Validation and Verfication of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guidance	原採認標準
422	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01139	EN	EN 13532	2012	General requirements for in vitro diagnostic medical devices for self-testing	原採認標準
423	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01143	IEC	IEC 61326-2-6:2012 ed2.0	2012	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment - Edition 2.0	原採認標準
424	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01144	ISO	ISO 15193:2009	2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures - Second Edition	原採認標準
425	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01145	ISO	ISO 15194:2009	2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation - Second Edition	原採認標準

426	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01146	ISO	ISO 15197:2013	2013	In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	原採認標準
427	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01147	ISO	ISO 18113-1:2009	2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements - First Edition	原採認標準
428	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01148	ISO	ISO 18113-2:2009	2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use - First Edition	原採認標準
429	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01149	ISO	ISO 18113-3:2009	2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use - First Edition	原採認標準
430	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01150	ISO	ISO 18113-4:2009	2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing - First Edition	原採認標準
431	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01151	ISO	ISO 18113-5:2009	2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing - First Edition	原採認標準
432	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01455	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	原採認標準
433	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01560	CLSI	AUTO11-A2	2014	Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard - Second Edition; Vol 34; No 17	原採認標準

434	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01561	CLSI	C24	2016	Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions	原採認標準
435	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01562	CLSI	C62-A	2014	Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline - Vol 34; No 16	原採認標準
436	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01563	CLSI	EP05-A3	2014	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline	原採認標準
437	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01564	CLSI	EP14-A3	2014	Evaluation of Matrix Effects; Approved Guideline	原採認標準
438	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01565	CLSI	EP15-A3	2014	User Verification of Performance for Precision and Trueness; Approved Guideline	原採認標準
439	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01566	CLSI	EP19	2015	A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures - Second Edition; Vol 35; No 10	原採認標準
440	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01567	CLSI	EP21	2016	Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures	原採認標準
441	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01568	CLSI	I/LA20	2016	Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities	原採認標準
442	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01571	CLSI	MM03	2015	Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline	原採認標準
443	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01572	CLSI	MM21	2015	Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications	原採認標準
444	7 In Vitro Diagnostics 體外診斷醫療器材	TFDA-01573	CLSI	POCT04	2016	Essential Tools for Implementation and Management of a Point-of-Care Testing Program - Third Edition	原採認標準

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

643	11 Orthopaedics 骨科學	TFDA-02056	ASTM	ASTM F1357 - 14(2019)	2019	Standard Specification for Articulating Total Wrist Implants	109 年度新增採認標準
644	11 Orthopaedics 骨科學	TFDA-02057	ASTM	ASTM F1611 - 20	2020	Standard Specification for Intramedullary Reamers	109 年度新增採認標準
645	11 Orthopaedics 骨科學	TFDA-02058	ASTM	ASTM F2385 - 15(2019)	2019	Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs	109 年度新增採認標準
646	11 Orthopaedics 骨科學	TFDA-02059	ISO	ISO 14243-3:2014/AMD 1:2020	2020	Implants for surgery - Wear of total knee-joint prostheses - Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test - Second Edition	109 年度新增採認標準
647	11 Orthopaedics 骨科學	TFDA-02060	ASTM	ASTM E399 - 20	2020	Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness KIc of Metallic Materials	109 年度新增採認標準
648	12 Physical Medicine 物理醫學科學	TFDA-00157	ISO	ISO 7176-7:1998	1998	Wheelchairs -- Part 7: Measurement of seating and wheel dimensions	原採認標準
649	12 Physical Medicine 物理醫學科學	TFDA-00162	ISO	ISO 7176-13:1989	1989	Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces	原採認標準
650	12 Physical Medicine 物理醫學科學	TFDA-00164	ISO	ISO 7176-15:1996	1996	Wheelchairs - Part 15: Requirements for Information Disclosure, Documentation and Labelling	原採認標準
651	12 Physical Medicine 物理醫學科學	TFDA-00792	CNS	CNS 15037-1	2006	雙臂操作步行輔具－要求及測試法－第 1 部：助行器	原採認標準
652	12 Physical Medicine 物理醫學科學	TFDA-00793	CNS	CNS 15037-2	2006	雙臂操作步行輔具－要求及測試法－第 2 部：帶輪助行器	原採認標準

653	12 Physical Medicine 物理醫學科學	TFDA-00794	CNS	CNS 15037-3	2006	雙臂操作步行輔具－要求及測試法－第 3 部：附前臂支撐桌助行器	原採認標準
654	12 Physical Medicine 物理醫學科學	TFDA-00795	CNS	CNS 15024-4	2006	單臂操作之步行輔具－要求與測試方法－第 4 部：三腳或多腳步行手杖	原採認標準
655	12 Physical Medicine 物理醫學科學	TFDA-00796	CNS	CNS 14103-1	2009	義肢學與矯具學－詞彙－第 1 部：外用義肢與外用矯具之一般術語	原採認標準
656	12 Physical Medicine 物理醫學科學	TFDA-00797	CNS	CNS 14103-2	2009	義肢學與矯具學－詞彙－第 2 部：外用義肢與其穿戴者之術語	原採認標準
657	12 Physical Medicine 物理醫學科學	TFDA-00798	CNS	CNS 14103-3	2009	義肢學與矯具學－詞彙－第 3 部：外用矯具之術語	原採認標準
658	12 Physical Medicine 物理醫學科學	TFDA-00799	CNS	CNS 14104-1	2009	義肢學與矯具學－肢體缺陷－第 1 部：先天性肢體缺陷之描述	原採認標準
659	12 Physical Medicine 物理醫學科學	TFDA-00800	CNS	CNS 14104-2	2009	義肢學與矯具學－肢體缺陷－第 2 部：下肢截肢之描述	原採認標準
660	12 Physical Medicine 物理醫學科學	TFDA-00801	CNS	CNS 14104-3	2009	義肢學與矯具學－肢體缺陷－第 3 部：上肢截肢之描述	原採認標準
661	12 Physical Medicine 物理醫學科學	TFDA-00802	CNS	CNS 14104-4	2009	義肢學與矯具學－肢體缺陷－第 4 部：導致截肢原因之描述	原採認標準
662	12 Physical Medicine 物理醫學科學	TFDA-00803	CNS	CNS 14104-5	2009	義肢學與矯具學－肢體缺陷－第 5 部：截肢病患臨床狀態之描述	原採認標準
663	12 Physical Medicine 物理醫學科學	TFDA-00804	CNS	CNS 15265-1	2009	義肢學與矯具學－義肢組件之分類與描述－第 1 部：義肢組件之分類	原採認標準
664	12 Physical Medicine 物理醫學科學	TFDA-00805	CNS	CNS 15265-2	2009	義肢學與矯具學－義肢組件之分類與描述－第 2 部：下肢義肢組件之描述	原採認標準

665	12 Physical Medicine 物理醫學科學	TFDA-00806	CNS	CNS 15265-3	2009	義肢學與矯具學－義肢組件之分類與描述－第 3 部：上肢義肢組件之描述	原採認標準
666	12 Physical Medicine 物理醫學科學	TFDA-00807	CNS	CNS 15266	2009	義肢學—髖關節結構之測試方法	原採認標準
667	12 Physical Medicine 物理醫學科學	TFDA-00808	CNS	CNS 15268	2009	外用義肢與外用矯具－要求與測試方法	原採認標準
668	12 Physical Medicine 物理醫學科學	TFDA-00809	CNS	CNS 15269	2009	義肢學－下肢義肢結構測試－要求與測試方法	原採認標準
669	12 Physical Medicine 物理醫學科學	TFDA-00810	CNS	CNS 14964	2007	輪椅－應用指導綱要	原採認標準
670	12 Physical Medicine 物理醫學科學	TFDA-00811	CNS	CNS 14964-1	2017	輪椅－第 1 部：靜態穩定性之測定	原採認標準
671	12 Physical Medicine 物理醫學科學	TFDA-00812	CNS	CNS 14964-2	2007	輪椅－第 2 部：動態穩定性之測定	原採認標準
672	12 Physical Medicine 物理醫學科學	TFDA-00814	CNS	CNS 14964-4	2017	輪椅－第 4 部：電動輪椅及代步車之耗能－理論行駛距離之測定	原採認標準
673	12 Physical Medicine 物理醫學科學	TFDA-00815	CNS	CNS 14964-6	2005	輪椅－第 6 部：電動輪椅最大速度、加速度與減速度之測定	原採認標準
674	12 Physical Medicine 物理醫學科學	TFDA-00816	CNS	CNS 14964-7	2006	輪椅－第 7 部：座椅及輪子尺度之量測	原採認標準
675	12 Physical Medicine 物理醫學科學	TFDA-00817	CNS	CNS 14964-8	2018	輪椅－第 8 部：輪椅靜力、衝擊與疲勞強度測試方法與要求	原採認標準
676	12 Physical Medicine 物理醫學科學	TFDA-00819	CNS	CNS 14964-10	2017	輪椅－第 10 部：電動輪椅越障能力試驗	原採認標準

677	12 Physical Medicine 物理醫學科學	TFDA-00821	CNS	CNS 14964-13	2006	輪椅－第 13 部：測試表面摩擦係數之測定	原採認標準
678	12 Physical Medicine 物理醫學科學	TFDA-00822	CNS	CNS 14964-14	2005	輪椅－第 14 部：電動輪椅之電力與控制系統測試方法與要求	原採認標準
679	12 Physical Medicine 物理醫學科學	TFDA-00823	CNS	CNS 14964-15	2007	輪椅－第 15 部：資訊宣告、文件與標示之要求	原採認標準
680	12 Physical Medicine 物理醫學科學	TFDA-00825	CNS	CNS 14964-19	2013	輪椅－第 19 部：機動車輛使用之輪型移動裝置	原採認標準
681	12 Physical Medicine 物理醫學科學	TFDA-00826	CNS	CNS 14964-21	2019	輪椅－第 21 部：電動輪椅及電動代步車之電磁相容性要求和測試方法	原採認標準
682	12 Physical Medicine 物理醫學科學	TFDA-00827	CNS	CNS 14964-22	2007	輪椅－第 22 部：設定程序	原採認標準
683	12 Physical Medicine 物理醫學科學	TFDA-00935	ISO	ISO 7176-4:2008	2008	Wheelchairs -- Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	原採認標準
684	12 Physical Medicine 物理醫學科學	TFDA-00936	ISO	ISO 7176-5:2008	2008	Wheelchairs -- Part 5: Determination of dimensions, mass and manoeuvring space	原採認標準
685	12 Physical Medicine 物理醫學科學	TFDA-00937	ISO	ISO 7176-9:2009	2009	Wheelchairs -- Part 9: Climatic tests for electric wheelchairs	原採認標準
686	12 Physical Medicine 物理醫學科學	TFDA-00938	ISO	ISO 7176-10:2008	2008	Wheelchairs -- Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs	原採認標準
687	12 Physical Medicine 物理醫學科學	TFDA-00939	ISO	ISO 7176-14:2008	2008	Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods	原採認標準

688	12 Physical Medicine 物理醫學科學	TFDA-00940	ISO	ISO 7176-21:2009	2009	Wheelchairs -- Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	原採認標準
689	12 Physical Medicine 物理醫學科學	TFDA-01383	CNS	CNS 15469-1	2011	步行輔具杖端－要求與試驗方法－第 1 部：杖端摩擦力 (Tips for assistive products for walking - Requirements and test methods - Part 1: Friction of tips) (IDT: ISO 24415-1:2009)	原採認標準
690	12 Physical Medicine 物理醫學科學	TFDA-01384	CNS	CNS 15469-2	2013	步行輔具杖端－要求與試驗方法－第 2 部：拐杖杖端耐用性 Tips for assistive products for walking − Requirements and test methods − Part 2: Durability of tips for crutches (IDT: ISO 24415-2:2011)	原採認標準
691	12 Physical Medicine 物理醫學科學	TFDA-01385	ISO	ISO 7176-11:2012	2012	Wheelchairs -- Part 11: Test dummies	原採認標準
692	12 Physical Medicine 物理醫學科學	TFDA-01386	ISO	ISO 7176-16:2012	2012	Wheelchairs -- Part 16: Resistance to ignition of postural support devices	原採認標準
693	12 Physical Medicine 物理醫學科學	TFDA-01387	ISO	ISO 7176-3:2012	2012	Wheelchairs -- Part 3: Determination of effectiveness of brakes	原採認標準
694	12 Physical Medicine 物理醫學科學	TFDA-01388	CNS	CNS 15677-1	2013	失能者或生理障礙者之技術系統和輔具－ 輪椅束縛裝置和乘坐者安全拘束系統－ 第 1 部：全部系統之要求及測試方法 (Technical systems and aids for disabled or handicapped persons − Wheelchair tiedown and occupant-restraint systems − Part 1: Requirements and test methods for all systems)	原採認標準
695	12 Physical Medicine 物理醫學科學	TFDA-01642	CNS	CNS 14964-16	2014	輪椅－第 16 部：姿勢支撐裝置之耐燃性(Wheelchairs − Part 16: Resistance to ignition of postural support devices)	原採認標準
696	12 Physical Medicine 物理醫學科學	TFDA-01643	CNS	CNS 14964-25	2014	輪椅－第 25 部：電動輪椅之電池組及充電器(Wheelchairs − Part 25: Batteries and chargers for powered wheelchairs)	原採認標準

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

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

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

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

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

745	13 Software/Informatics 軟體/醫療資訊	TFDA-00972	CNS	CNS 14232-14	2010	健康資訊交換第七層協定－第 14 部：應用管理	原採認標準
746	13 Software/Informatics 軟體/醫療資訊	TFDA-00973	CNS	CNS 14232-15	2010	健康資訊交換第七層協定－第 15 部：人事管理	原採認標準
747	13 Software/Informatics 軟體/醫療資訊	TFDA-01052	AAMI	AAMI SW87:2012	2012	Application of quality management system concepts to medical device data systems	原採認標準
748	13 Software/Informatics 軟體/醫療資訊	TFDA-01054	AAMI	AAMI TIR80001-2-1:2012	2012	Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples	原採認標準
749	13 Software/Informatics 軟體/醫療資訊	TFDA-01055	AAMI	AAMI TIR80001-2-2:2012	2012	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls	原採認標準
750	13 Software/Informatics 軟體/醫療資訊	TFDA-01056	AAMI	AAMI TIR80001-2-3:2012	2012	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks	原採認標準
751	13 Software/Informatics 軟體/醫療資訊	TFDA-01057	AAMI	AAMI TIR80001-2-4:2012	2012	Application of risk management for IT-networks incorporating medical devices ─ Part 2-4: General implementation guidance for healthcare delivery organizations	原採認標準
752	13 Software/Informatics 軟體/醫療資訊	TFDA-01059	CNS	CNS 14232-16	2010	健康資訊交換第七層協定－第１６部：附錄 (Health Level Seven (HL7) - Part 16: Appendix)	原採認標準

753	13 Software/Informatics 軟體/醫療資訊	TFDA-01060	CNS	CNS 14232-2	2010	健康資訊交換第七層協定－第２部：控制 (Health Level Seven (HL7) - Part 2: Control)	原採認標準
754	13 Software/Informatics 軟體/醫療資訊	TFDA-01061	CNS	CNS 14232-3	2010	健康資訊交換第七層協定－第３部：病患管理 (Health Level Seven (HL7) - Part 3: Patient administration)	原採認標準
755	13 Software/Informatics 軟體/醫療資訊	TFDA-01062	IEC	IEC 62443-2-1 ed1.0	2010	Industrial communication networks—Network and system security—Part 2–1: Establishing an industrial automation and control system security program.	原採認標準
756	13 Software/Informatics 軟體/醫療資訊	TFDA-01063	IEC	IEC 80001-1:2010	2010	Application of risk management for IT Networks incorporating medical devices — Part 1: Roles, responsibilities and activities	原採認標準
757	13 Software/Informatics 軟體/醫療資訊	TFDA-01064	IEC	IEC/TIR 80002-1:2009	2009	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software - Edition 1.0	原採認標準
758	13 Software/Informatics 軟體/醫療資訊	TFDA-01065	IEC	IEC/TR 62443-3-1 ed1.0	2009	Industrial communication networks—Network and system security—Part 3–1: Security technologies for industrial automation and control systems.	原採認標準
759	13 Software/Informatics 軟體/醫療資訊	TFDA-01067	IEC	IEC/TS 62443-1-1 ed1.0	2009	Industrial communication networks—Network and system security—Part 1–1: Terminology,concepts and models	原採認標準
760	13 Software/Informatics 軟體/醫療資訊	TFDA-01069	ISO	ISO/IEC 15026-4:2012	2012	Systems and Software Engineering--Systems and SoftwareAssurance--Part 4: Assurance in the Life Cycle	原採認標準

761	13 Software/Informatics 軟體/醫療資訊	TFDA-01070	ISO	ISO/IEC 25001:2014	2014	Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Planning and management - Second Edition	原採認標準
762	13 Software/Informatics 軟體/醫療資訊	TFDA-01071	ISO	ISO/IEC 25051:2014	2014	Software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing - Second Edition	原採認標準
763	13 Software/Informatics 軟體/醫療資訊	TFDA-01074	ISO	ISO/IEEE 11073-10404:2010	2010	Health informatics Personal health device communication Part 10404: Device specialization Pulse oximeter	原採認標準
764	13 Software/Informatics 軟體/醫療資訊	TFDA-01075	ISO	ISO/IEEE 11073-10406:2012	2011	Health informatics--Personal health device communication Part 10406: Device specialization--Basic electrocardiograph (ECG) (1- to 3-lead ECG)	原採認標準
765	13 Software/Informatics 軟體/醫療資訊	TFDA-01076	ISO	ISO/IEEE 11073-10407:2010	2010	ISO/IEEE Health informatics Personal health device communication Part 10407: Device specialization Blood pressure monitor	原採認標準
766	13 Software/Informatics 軟體/醫療資訊	TFDA-01077	ISO	ISO/IEEE 11073-10408:2010	2010	Health Informatics-Personal Health Device Communication Part 10408: Device Specialization-Thermometer	原採認標準
767	13 Software/Informatics 軟體/醫療資訊	TFDA-01078	ISO	ISO/IEEE 11073-10415:2010	2010	Health Informatics-Personal Health Device Communication Part 10415: Device Specialization-Weighing Scale	原採認標準
768	13 Software/Informatics 軟體/醫療資訊	TFDA-01082	ISO	ISO/IEEE 11073-10472:2012	2012	Health Informatics—Personal health device communication—Part 10472 Device specialization—Medication monitor	原採認標準

769	13 Software/Informatics 軟體/醫療資訊	TFDA-01083	ISO	ISO/IEEE 11073-20101:2004	2004	IEEE Standard for Health Informatics - Point-Of-Care Medical Device Communication - Part 20101: Application Profile - Base Standard	原採認標準
770	13 Software/Informatics 軟體/醫療資訊	TFDA-01664	IEC	IEC 62304:2006+A1:2015	2015	Medical device software - Software life cycle processes	原採認標準
771	13 Software/Informatics 軟體/醫療資訊	TFDA-01665	IEC	IEC 82304-1:2016	2016	Health software - Part 1: General requirements for product safety - Edition 1.0	原採認標準
772	13 Software/Informatics 軟體/醫療資訊	TFDA-01666	IEC	IEC/TR 80001-2-5:2014	2014	Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems - Edition 1.0	原採認標準
773	13 Software/Informatics 軟體/醫療資訊	TFDA-01667	IEC	IEC/TR 80002-3:2014	2014	Medical device software –Part 3: Process reference model of medical device software life cycle processes (IEC 62304)	原採認標準
774	13 Software/Informatics 軟體/醫療資訊	TFDA-01668	IEEE	IEEE Std 11073-10417-2015	2015	Health Informatics-Personal health device communication Part 10417: Device specialization-Glucose meter	原採認標準
775	13 Software/Informatics 軟體/醫療資訊	TFDA-01669	IEEE	IEEE Std 11073-10422-2016	2016	Health informatics-Personal health device communication Part 10422: Device specialization - Urine analyzer	原採認標準
776	13 Software/Informatics 軟體/醫療資訊	TFDA-01670	IEEE	IEEE Std 11073-10424-2014	2014	Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE)	原採認標準

777	13 Software/Informatics 軟體/醫療資訊	TFDA-01674	IEEE	IEEE Std 3333.2.1-2015	2015	IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling	原採認標準
778	13 Software/Informatics 軟體/醫療資訊	TFDA-01675	ISO	ISO TIR 80001-2-6:2014	2014	Application of risk management for Itnetworks incorporating medical — Application guidance — Part 2-6: Guidance for responsibility agreements	原採認標準
779	13 Software/Informatics 軟體/醫療資訊	TFDA-01676	ISO	ISO TIR 80002-2:2017	2017	Medical device software - Part 2: Validation of software for medical device quality systems	原採認標準
780	13 Software/Informatics 軟體/醫療資訊	TFDA-01677	ISO	ISO/IEEE 11073-10102:2012	2012	Health informatics—Personal health device communication Part 10102: Nomenclature—Annotated ECG	原採認標準
781	13 Software/Informatics 軟體/醫療資訊	TFDA-01679	ISO	ISO/IEEE 11073-10421:2012	2012	Health informatics—Personal health device communication Part 10421: Device specialization—Peak expiratory flow monitor (peak flow)	原採認標準
782	13 Software/Informatics 軟體/醫療資訊	TFDA-01852	IEEE	IEEE 1012:2016	2016	IEEE Standard for System and Software Verification and Validation	原採認標準
783	13 Software/Informatics 軟體/醫療資訊	TFDA-01854	IEEE	IEEE 11073-10425:2017	2017	Health informatics—Personal health device communication Part 10425: Device Specialization—Continuous Glucose Monitor (CGM)	原採認標準
784	13 Software/Informatics 軟體/醫療資訊	TFDA-01855	IEEE	IEEE 11073-20601:2016	2016	Health informatics--Personal health device communication Part 20601: Application profile-Optimized Exchange Protocol.	原採認標準

785	13 Software/Informatics 軟體/醫療資訊	TFDA-01856	IEEE	IEEE/IEC/ISO 12207:2017	2017	Systems and software engineering -- Software life cycle processes	原採認標準
786	13 Software/Informatics 軟體/醫療資訊	TFDA-01857	ISO	ISO/IEEE 11073-10102:2014	2014	Health informatics -- Point-of-care medical device communication Part 10102: Nomenclature --Annotated ECG	原採認標準
787	13 Software/Informatics 軟體/醫療資訊	TFDA-01858	ISO	ISO/IEEE 11073-10417:2017	2017	IEEE Health informatics -- Personal health device communication Part 10417: Device Specialization -- Glucose Meter	原採認標準
788	13 Software/Informatics 軟體/醫療資訊	TFDA-01915	AAMI	AAMI TIR45:2012/(R)2018	2018	Guidance on the use of AGILE practices in the development of medical device software	原採認標準
789	13 Software/Informatics 軟體/醫療資訊	TFDA-01916	ASTM	ASTM F2761-09(2013)	2013	Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model	原採認標準
790	13 Software/Informatics 軟體/醫療資訊	TFDA-01917	ISO	ISO/IEEE 11073-10418:2014/COR 1:2016	2016	Health informatics—Personal health device communication—Part 10418 Device specialization—International normalized ratio (INR) monitor	原採認標準
791	13 Software/Informatics 軟體/醫療資訊	TFDA-01918	IEEE	IEEE Std 11073-10424-2014/Cor 1-2017	2017	Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE)	原採認標準
792	13 Software/Informatics 軟體/醫療資訊	TFDA-02065	ISO	ISO/IEEE 11073-10101+A11:2017	2017	ISO/IEEE Health Informatics - Point-Of-Care Medical Device Communication - Part 10101: Nomenclature	109 年度新增採認標準

793	13 Software/Informatics 軟體/醫療資訊	TFDA-02066	IEEE	IEEE Std 11073-10207-2017	2017	Health informatics—Point-of-care medical device communication Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication.	109 年度新增採認標準
794	13 Software/Informatics 軟體/醫療資訊	TFDA-02067	ISO	ISO/IEEE 11073-20702-2018	2018	Health informatics—Point-of-care medical device communication—Part 20702: Medical devices communication profile for web services	109 年度新增採認標準
795	13 Software/Informatics 軟體/醫療資訊	TFDA-02068	ISO	ISO/IEEE 11073-10201:2020	2020	ISO/IEEE Health Informatics - Point-Of-Care Medical Device Communication - Part 10201: Domain Information Model	109 年度新增採認標準
796	13 Software/Informatics 軟體/醫療資訊	TFDA-02069	AAMI	AAMI TIR57:2016/(R)2019	2019	Principles for medical device security—Risk management	109 年度新增採認標準
797	14 Radiology 放射學科學	TFDA-00282	ISO	ISO 12005:2003	2003	Lasers and laser-related equipment - Test methods for laser beam parameters - Polarization	原採認標準
798	14 Radiology 放射學科學	TFDA-00283	ISO	ISO 13696:2002	2004	Optics and optical instruments -- Test methods for radiation scattered by optical components	原採認標準
799	14 Radiology 放射學科學	TFDA-00412	IEC	IEC 61847: 1998	1998	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics Ed. 1.0	原採認標準
800	14 Radiology 放射學科學	TFDA-00414	ISO	ISO 11146-2:2005	2005	Lasers and laser-related equipment - Test methods for laser beam widths, divergence angles and beam propagation ratios - Part 2: General astigmatic beams	原採認標準

801	14 Radiology 放射學科學	TFDA-00415	ISO	ISO/TR 11146-3:2004/Cor 1:2005	2005	Lasers and laser-related equipment -- Test methods for laser beam widths, divergence angles and beam propagation ratios -- Part 3: Intrinsic and geometrical laser beam classification, propagation and details of test methods	原採認標準
802	14 Radiology 放射學科學	TFDA-00417	ISO	ISO 9236-1:2004	2004	Photography - Sensitometry of screen/film systems for medical radiography - Part 1: Determination of sensitometric curve shape, speed and average gradient	原採認標準
803	14 Radiology 放射學科學	TFDA-00418	ISO	ISO 4090:2001	2001	Photography - Medical radiographic cassette/screens/films and hard-copy imaging films - Dimensions and specifications	原採認標準
804	14 Radiology 放射學科學	TFDA-00419	ISO	ISO 5799:1991	1991	Photography -- Direct-exposing medical and dental radiographic film/process systems -- Determination of ISO speed and ISO average gradient	原採認標準
805	14 Radiology 放射學科學	TFDA-00421	ISO	ISO 15367-1:2003	2003	Lasers and laser-related equipment -- Test methods for determination of the shape of a laser beam wavefront -- Part 1: Terminology and fundamental aspects	原採認標準
806	14 Radiology 放射學科學	TFDA-00422	ISO	ISO 15367-2:2005	2005	Lasers and laser-related equipment - Test methods for determination of the shape of a laser beam wavefront - Part 2: Shack-Hartman sensors	原採認標準
807	14 Radiology 放射學科學	TFDA-00431	IEC	IEC/TR 60825-14 - Ed. 1.0	2004	Safety of laser products - Part 14: A user's guide	原採認標準
808	14 Radiology 放射學科學	TFDA-00584	IEC	IEC/TR 60825-8:2006	2006	Safety of laser products - Part 8: Guidelines for the safe use of laser beams on humans	原採認標準
809	14 Radiology 放射學科學	TFDA-00730	IEC	IEC 60601-2-29:2008 Edition 3.0	2008	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	原採認標準

810	14 Radiology 放射學科學	TFDA-00731	ISO	ISO 11670:2003 /Cor1:2004	2004	Lasers and laser-related equipment -- Test methods for laser beam parameters -- Beam positional stability	原採認標準
811	14 Radiology 放射學科學	TFDA-00747	CNS	CNS 15211	2010	健康資訊學－醫學數位影像及通信暨工作流程及資料處理	原採認標準
812	14 Radiology 放射學科學	TFDA-00896	IEC	IEC 60601-2-5:2009 ed3.0	2009	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	原採認標準
813	14 Radiology 放射學科學	TFDA-00898	IEC	IEC/TR 60825-3:2008 ed2.0	2008	Safety of laser products - Part 3: Guidance for laser displays and shows	原採認標準
814	14 Radiology 放射學科學	TFDA-00974	IEC	IEC 60976:2007 ed2.0	2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	原採認標準
815	14 Radiology 放射學科學	TFDA-01245	ISO	ISO 21254-3:2011	2011	Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Part 3: Assurance of laser power (energy) handling capabilities - First Edition	原採認標準
816	14 Radiology 放射學科學	TFDA-01247	ISO	ISO TR 21254-4:2011	2011	Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Part 4: Inspection, detection and measurement - First Edition	原採認標準
817	14 Radiology 放射學科學	TFDA-01390	CNS	CNS 15584	2013	X 射線管組件之永久過濾測定 (Determination of the permanent filtration of X-ray tube assemblies (IDT: IEC 60522:1999))	原採認標準
818	14 Radiology 放射學科學	TFDA-01392	CNS	CNS 15586	2013	醫電設備電性安全－醫用診斷 X 射線管組件－焦斑特性 (Medical electrical equipment – X-ray tube assemblies for medical diagnosis –Characteristics of focal spots (IDT: IEC 60336:2005))	原採認標準

819	14 Radiology 放射學科學	TFDA-01393	CNS	CNS 15587	2013	醫用診斷 X 射線設備－用於測定特性的輻射條件 (Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics (IDT: IEC 61267:2005))	原採認標準
820	14 Radiology 放射學科學	TFDA-01394	IEC	IEC 60601-1-3:2013	2013	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment - Edition 2.1; Consolidated Reprint	原採認標準
821	14 Radiology 放射學科學	TFDA-01395	IEC	IEC 60601-2-11:2013	2013	Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment - Edition 3.0	原採認標準
822	14 Radiology 放射學科學	TFDA-01404	IEC	IEC 60627:2013	2013	Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids - Edition 3.0	原採認標準
823	14 Radiology 放射學科學	TFDA-01406	IEC	IEC 60825-1:2014 ed3.0	2014	Safety of laser products – Part 1: Equipment classification and requirements - Edition 3.0	原採認標準
824	14 Radiology 放射學科學	TFDA-01407	IEC	IEC 60825-2:2010	2010	Safety of laser products – Part 2: Safety of optical fibre communication systems (OFCS) - Edition 3.2	原採認標準
825	14 Radiology 放射學科學	TFDA-01408	IEC	IEC 60825-4:2011	2011	Safety of laser products – Part 4: Laser guards - Edition 2.2	原採認標準
826	14 Radiology 放射學科學	TFDA-01409	IEC	IEC 61161:2013 ed3.0	2013	Ultrasonics—Power measurement—Radiation force balances and performance requirements.	原採認標準
827	14 Radiology 放射學科學	TFDA-01410	IEC	IEC 61217:2011	2011	Radiotherapy equipment – Coordinates, movements and scales - Edition 2.0	原採認標準

828	14 Radiology 放射學科學	TFDA-01412	IEC	IEC 61223-3-2:2007	2013	Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment - Edition 2.0	原採認標準
829	14 Radiology 放射學科學	TFDA-01413	IEC	IEC 61223-3-4:2000	2000	Evaluation and Routine Testing in Medical Imaging Departments - Part 3-4: Acceptance Tests - Imaging Performance of Dental X-Ray Equipment - Edition 1.0	原採認標準
830	14 Radiology 放射學科學	TFDA-01415	IEC	IEC 61331-1:2014	2014	Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials - Edition 2.0	原採認標準
831	14 Radiology 放射學科學	TFDA-01416	IEC	IEC 61331-2:2014	2014	Protective devices against diagnostic medical X-radiation – Part 2: Translucent protective plates - Edition 2.0	原採認標準
832	14 Radiology 放射學科學	TFDA-01417	IEC	IEC 61331-3:2014	2004	Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields - Edition 2.0	原採認標準
833	14 Radiology 放射學科學	TFDA-01418	IEC	IEC 61674:2012	2012	Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging - Edition 2.0	原採認標準
834	14 Radiology 放射學科學	TFDA-01419	IEC	IEC 61689:2013	2013	Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz - Edition 3.0	原採認標準
835	14 Radiology 放射學科學	TFDA-01420	IEC	IEC 62083:2009	2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	原採認標準
836	14 Radiology 放射學科學	TFDA-01421	IEC	IEC 62127-1 ed1.1 Consol. with am1	2013	Ultrasonics—Hydrophones—Part 1: Measurement and characterization of medical ultrasonic fields up to 40 megahertz (MHz).	原採認標準
837	14 Radiology 放射學科學	TFDA-01423	IEC	IEC 62127-3 ed1.1 Consol. with am1	2013	Ultrasonics—Hydrophones—Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz.	原採認標準

838	14 Radiology 放射學科學	TFDA-01424	IEC	IEC 62555:2013 ed1.0	2013	Ultrasonics—Power measurement—High intensity therapeutic ultrasound (HITU) transducers and systems	原採認標準
839	14 Radiology 放射學科學	TFDA-01426	IEEE	IEEE N42.13, 2004	2004	Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides	原採認標準
840	14 Radiology 放射學科學	TFDA-01427	ISO	ISO 11146-1:2005	2005	Lasers and laser-related equipment -- Test methods for laser beam widths, divergence angles and beam propagation ratios -- Part 1: Stigmatic and simple astigmatic beams	原採認標準
841	14 Radiology 放射學科學	TFDA-01428	ISO	ISO 21254-1:2011	2011	Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 1: Definitions and general principles	原採認標準
842	14 Radiology 放射學科學	TFDA-01429	ISO	ISO 21254-2:2011	2011	Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 2: Threshold determination	原採認標準
843	14 Radiology 放射學科學	TFDA-01430	ISO	ISO 2919:2012	2012	Radiological protection -- Sealed radioactive sources -- General requirements and classification	原採認標準
844	14 Radiology 放射學科學	TFDA-01431	ISO	ISO/ASTM 51275:2013	2013	Practice for use of a radiochromic film dosimetry system	原採認標準
845	14 Radiology 放射學科學	TFDA-01432	ISO	ISO/ASTM 51607:2013	2013	Practice for use of an alanine-EPR dosimetry system	原採認標準
846	14 Radiology 放射學科學	TFDA-01681	ASTM	ASTM F2978-13	2013	Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging	原採認標準
847	14 Radiology 放射學科學	TFDA-01701	EN	EN 62220-1-1:2015	2015	Medical electrical equipment - Characteristics of digital x-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging	原採認標準

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

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

863	14 Radiology 放射學科學	TFDA-01859	IEC	IEC 60601-2-28:2017	2017	Medical electrical equipment - Part 2-28:Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	原採認標準
864	14 Radiology 放射學科學	TFDA-01861	IEC	IEC 60601-2-63:2017	2017	Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment	原採認標準
865	14 Radiology 放射學科學	TFDA-01862	IEC	IEC 60601-2-65:2017	2017	Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment	原採認標準
866	14 Radiology 放射學科學	TFDA-01863	ISO	ISO 11554:2017	2017	Optics and photonics -- Lasers and laser-related equipment -- Test methods for laser beam power, energy and temporal characteristics	原採認標準
867	14 Radiology 放射學科學	TFDA-01864	ISO	ISO 12052:2017	2017	Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management	原採認標準
868	14 Radiology 放射學科學	TFDA-01919	IEC	IEC 60601-2-54:2009 +AMD1:2015+AMD 2:2018 CSV	2018	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	原採認標準
869	14 Radiology 放射學科學	TFDA-01920	ISO	ISO 11670:2003 /COR 1:2004	2004	Lasers and laser-related equipment - Test methods for laser beam parameters - Beam positional stability	原採認標準
870	14 Radiology 放射學科學	TFDA-01921	ASTM	ASTM D7866-14a	2014	Standard Specification for Radiation Attenuating Protective Gloves	原採認標準
871	14 Radiology 放射學科學	TFDA-02070	IEC	EC 61223-3-5:2019	2019	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment	109 年度新增採認標準

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

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

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

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

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

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

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

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

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

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

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

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

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

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