衛生福利部食品藥物管理署醫療器材標準採認公告

附件 2、本署過去曾公告採認醫療器材標準清單

說明:

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

表 一、109 年度已廢除/改版之醫療器材標準共 220 項

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

						requirements	COR1:2019)
109	8 Materials 材料	TFDA-00065	ISO	ISO 13782:1996	1996	Implants for surgery -- Metallic materials -- Unalloyed tantalum for surgical implant applications	本標準已改版，請參考新版本標準。(ISO 13782:2019)
110	8 Materials 材料	TFDA-00073	ISO	ISO 5832-8:1997	1997	Implants for surgery -- Metallic materials -- Part 8: Wrought cobalt-nickel-chromium-molybdenum- tungsten-iron alloy	原採認標準已廢除
111	8 Materials 材料	TFDA-00556	CNS	CNS 13382-18	1995	外科植入物–生物相容性–材料及器材之生物檢測方法的選擇（準則）	原採認標準已廢除
112	8 Materials 材料	TFDA-00562	CNS	CNS 13382-24	1996	外科植入物–超高分子量聚乙烯（第一部分：粉狀）	原採認標準已廢除
113	8 Materials 材料	TFDA-00563	CNS	CNS 13382-25	1996	外科植入物–超高分子量聚乙烯（第二部分：成形材）	原採認標準已廢除
114	8 Materials 材料	TFDA-00952	AAMI	ST65:2008	2008	Processing of reusable surgical textiles for use in health care facilities	本標準已改版，請參考新版本標準。(AAMI ST65:2008 (R2018))
115	8 Materials 材料	TFDA-00956	ISO	ISO 13938-1:1999	1999	Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension	本標準已改版，請參考新版本標準。(ISO 13938-1:2019)
116	8 Materials 材料	TFDA-01087	ASTM	ASTM F1091-12	2012	Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10 Nickel Alloy Surgical Fixation Wire	本標準已改版，請參考新版本標準。(ASTM F1091 - 20)

						(UNS R30605)	
117	8 Materials 材料	TFDA-01089	ASTM	ASTM F139-12	2012	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	本標準已改版，請參考新版本標準。(ASTM F139 - 19)
118	8 Materials 材料	TFDA-01090	ASTM	ASTM F1537-11	2011	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	本標準已改版，請參考新版本標準。(ASTM F1537 - 20)
119	8 Materials 材料	TFDA-01094	ASTM	ASTM F2393-12	2012	Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications	本標準已改版，請參考新版本標準。(ASTM F2393 - 12(2016))
120	8 Materials 材料	TFDA-01097	ASTM	ASTM F621-12	2012	Standard Specification for Stainless Steel Forgings for Surgical Implants	本標準已改版，請參考新版本標準。(ASTM F621 - 12(2017))
121	8 Materials 材料	TFDA-01098	ASTM	ASTM F899-12b	2012	Standard Specification for Wrought Stainless Steels for Surgical Instruments	本標準已改版，請參考新版本標準。(ASTM F899 - 20)
122	8 Materials 材料	TFDA-01585	ASTM	ASTM F1581-08/(R)2012	2012	Standard Specification for Composition of Anorganic Bone for Surgical Implants	本標準已改版，請參考新版本標準。(ASTM F1581 - 08(2016))

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

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

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

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

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

							14(2019))
161	11 Orthopaedics 骨科學	TFDA-01621	ASTM	ASTM F1611-00/(R)2013	2013	Standard Specification for Intramedullary Reamers	本標準已改版，請參考新版本標準。(ASTM F1611 - 20)
162	11 Orthopaedics 骨科學	TFDA-01628	ASTM	ASTM F2385-15	2015	Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs	本標準已改版，請參考新版本標準。(ASTM F2385 - 15(2019))
163	11 Orthopaedics 骨科學	TFDA-01638	ISO	ISO 14243-3: 2014	2014	Implants for surgery - Wear of total knee-joint prostheses - Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test - Second Edition	本標準已改版，請參考新版本標準。(ISO 14243-3:2014/AMD 1:2020)
164	11 Orthopaedics 骨科學	TFDA-01834	ASTM	ASTM E399-17	2017	Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness KIc of Metallic Materials	本標準已改版，請參考新版本標準。(ASTM E399 - 20)
165	11 Orthopaedics 骨科學	TFDA-01835	ASTM	ASTM F1378-17	2017	Standard Specification for Shoulder Prostheses	本標準已改版，請參考新版本標準。(ASTM F1378 - 18e1)
166	11 Orthopaedics 骨科學	TFDA-01837	ASTM	ASTM F1717-15	2015	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	本標準已改版，請參考新版本標準。(ASTM F1717 - 18)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

						quantification of degradation products from polymeric	10993-13:2010)
142.	2 Biocompatibility 生物相容性	TFDA-00023	ISO	ISO 10993-16:1997	1997-09-01	Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables	本標準已改版，請參考新版本標準。(ISO 10993-16:2010)
143.	2 Biocompatibility 生物相容性	TFDA-00514	ISO	ISO 10993-3:2003	2003/10/15	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	本標準已改版，請參考新版本標準。(ISO 10993-3:2014)
144.	2 Biocompatibility 生物相容性	TFDA-00516	ISO	ISO 10993-6:2007	2007/04/04	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	本標準已改版，請參考新版本標準。(ISO 10993-6:2016)
145.	2 Biocompatibility 生物相容性	TFDA-00517	ISO	ISO 10993-10:2002/Amd 1:2006	2006-07-15	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity	本標準已改版，請參考新版本標準。(ISO 10993-10:2010)
146.	2 Biocompatibility 生物相容性	TFDA-00533	ISO	ISO/TS 20993:2006	2006-07-26	Biological evaluation of medical devices -- Guidance on a risk-management process	本標準已廢除，請參考新標準。(ISO 10993-1:2009/Cor1:2010)
147.	2 Biocompatibility 生物相容性	TFDA-00668	ISO	ISO 10993-12:2007	2008-2-15	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials	本標準已改版，請參考新版本標準。(ISO 10993-12:2012)
148.	2 Biocompatibility 生物相容性	TFDA-00726	ISO	ISO 10993-7：2008	2008-10-25	Biological evaluation of medical devices -- Part 7: Ethylene oxide	本標準已改版，請參考新版本標準。(ISO

						sterilization residuals	10993-7:2008/Cor 1:2009)
149.	3 Cardiovascular 心臟血管醫學	TFDA-00313	IEC	IEC 60601-2-31:1994	1998-01	Medical electrical equipment, Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source	本標準已改版，請參考新版本標準。(IEC 60601-2-31:2011 ed2.1 Consol. with am1)
150.	3 Cardiovascular 心臟血管醫學	TFDA-00315	IEC	IEC 60601-2-25	1999-05	Medical Electrical Equipment-Part 2, Particular Requirements for the Safety of Electrocardiographs	本標準已改版，請參考新版本標準。(IEC 60601-2-25:2011)
151.	3 Cardiovascular 心臟血管醫學	TFDA-00316	IEC	IEC 60601-2-47	2001-07	Medical Electrical Equipment Part 2-47: Particular Requirements for the Safety, including Essential Performance of Ambulatory Electrocardiographic Systems	本標準已改版，請參考新版本標準。(IEC 60601-2-47:2012 ed2.0)
152.	3 Cardiovascular 心臟血管醫學	TFDA-00317	IEC	IEC 60601-2-4	2002-08	Particular Requirements for the Safety of Cardiac Defibrillator	本標準已改版，請參考新版本標準。(IEC 60601-2-4:2010 ed3.0)
153.	3 Cardiovascular 心臟血管醫學	TFDA-00446	ISO	ISO 5840:2005	2005-03-07	Cardiovascular implants - Cardiac valve prostheses	本標準已改版，請參考新版本標準。(ISO 5840-1:2015)
154.	3 Cardiovascular 心臟血管醫學	TFDA-00447	ISO	ISO 14708-2: 2005	2005-10-01	Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers	本標準已改版，請參考新版本標準。(ISO 14708-2:2012)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

							11607-1:2009/Amd1:2014)
730.	15 Sterility 滅菌	TFDA-00026	ISO	ISO 11737-1:1995	1995-12-01	Sterilization of medical devices-microbiological methods-Part 1: Estimation of the population of microorganisms on product.	本標準已改版，請參考新版本標準。(ISO 11737-1:2006)
731.	15 Sterility 滅菌	TFDA-00028	ISO	ISO 13408-1:1998	1998-08-01	Aseptic processing of health care products -- Part 1: General requirements	本標準已改版，請參考新版本標準。(ISO 13408-1:2015)
732.	15 Sterility 滅菌	TFDA-00030	ISO	ISO 14160:1998	1998-03-15	Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants	本標準已改版，請參考新版本標準。(ISO 14160:2011)
733.	15 Sterility 滅菌	TFDA-00031	ISO	ISO 14161:2000	2000-10-01	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results, 2ed.	本標準已改版，請參考新版本標準。(ISO 14161:2009)
734.	15 Sterility 滅菌	TFDA-00032	ISO	ISO 14644-1:1999	1999-5-1	Cleanrooms and Associated Conrtolled Environments - Part 1: Classification of Air Cleanliness	本標準已改版，請參考新版本標準。(ISO 14644-1:2015)
735.	15 Sterility 滅菌	TFDA-00033	ISO	ISO 14644-2:2000	2000-9-15	Cleanrooms and Associated Controlled Environments - Part 2:	本標準已改版，請參考新版本標準。(ISO 14644-2:2015)

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

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

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

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

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

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

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

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

						of nerve and muscle stimulators	60601-2-10:2016)
787.	17 Neurology 神經學	TFDA-00606	ASTM	ASTM F647–94 (R2000)	1994-08-01	Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application	本標準已改版，請參考新版本標準。(ASTM F647-94/(R)2006)
788.	17 Neurology 神經學	TFDA-00608	ASTM	ASTM F1542-94 (R2000)	1994-10-01	Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips	本標準已廢除，無取代標準。
789.	17 Neurology 神經學	TFDA-00618	IEC	IEC 60601-2-23:1999	1999-12-10	Medical electrical equipment-Part 2-23:Particular requirements for the safety, including essential performance,of transcutaneous partial pressure monitoring equipment	本標準已改版，請參考新版本標準。(IEC 60601-2-23:2011)
790.	17 Neurology 神經學	TFDA-00628	ISO	ISO 7197:1997	1997-11-01	Neurosurgical implants — Sterile, single use hydrocephalus shunts and components	本標準已改版，請參考新版本標準。(ISO 7197:2006/Cor 1:2007)
791.	17 Neurology 神經學	TFDA-00630	AAMI	AAMI NS28:1988/(R)2001	2001-07-23	Intracranial pressure monitoring devices	本標準已改版，請參考新版本標準。(AAMI NS28:1988/(R)2010)
792.	17 Neurology 神經學	TFDA-00933	AAMI	NS28:1988/(R)2006	2009-7-26	Intracranial pressure monitoring devices	本標準已改版，請參考新版本標準。(AAMI NS28:1988/(R)2010)

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

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

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

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

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