附件 2、歷年廢除或改版之醫療器材標準清單

說明:

1. 本清單所列醫療器材標準，為本署過去曾公告採認，然因該項標準已被廢除或改版者，詳見備註說明欄。
2. 提供 104 年至 110 年廢除或改版之醫療器材標準共 1,154 項如下表。

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	Anesthesias 麻醉學	TFDA-00093	IEC	IEC 60601-3-1:1996	1996	Medical Electrical Equipment Part 3-1: Essential Performance Requirements for Transcutaneous Oxygen and Carbon Dioxide Partial Pressure Monitoring Equipment	本標準已廢除，無取代標準。
2	Anesthesias 麻醉學	TFDA-00094	ISO	ISO 5360:1993	1998	Anaesthetic vaporizers - Agent specific filling systems	本標準已改版，請參考新版本標準。(ISO 5360:2016)
3	Anesthesias 麻醉學	TFDA-00095	ISO	ISO 5361:1999	1999	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)
4	Anesthesias 麻醉學	TFDA-00096	ISO	ISO 5361-4:1987	1987	Tracheal Tubes - Part 4: Cole Type	本標準已改版，請參考新版本標準。(ISO 5361:2016)
5	Anesthesias 麻醉學	TFDA-00097	ISO	ISO 5362:2000	2000	Anaesthetic Reservoir Bags	本標準已改版，請參考新版本標準。(ISO 5362:2006)
6	Anesthesias 麻醉學	TFDA-00098	ISO	ISO 5366-1:2000	2000	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)
7	Anesthesias 麻醉學	TFDA-00099	ISO	ISO 5366-3:2001	2003	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)
8	Anesthesias 麻醉學	TFDA-00100	ISO	ISO 5367:2000	2000	Breathing Tubes intended for use with Anaesthetic Apparatus and Ventilators	本標準已改版，請參考新版本標準。(ISO 5367:2014)

9	Anesthesias 麻醉學	TFDA-00101	ISO	ISO 7767:1997	1997	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)
10	Anesthesias 麻醉學	TFDA-00102	ISO	ISO 8359:1996	1996	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)
11	Anesthesias 麻醉學	TFDA-00103	ISO	ISO 8382:1988	1988	Resuscitators Intended for Use with Humans	本標準已廢除，請參考新標準。(ISO 10651-5: 2006)
12	Anesthesias 麻醉學	TFDA-00104	ISO	ISO 9918:1993	1993	Capnometers for Use with Humans - Requirements	本標準已廢除，請參考新標準。(ISO 80601-2-55:2011)
13	Anesthesias 麻醉學	TFDA-00262	ASTM	ASTM F1850-00	2000	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)
14	Anesthesias 麻醉學	TFDA-00265	ASTM	ASTM F920-93(R1999)	1993	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)
15	Anesthesias 麻醉學	TFDA-00266	ASTM	ASTM F1100-90(R1997)	1990	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)
16	Anesthesias 麻醉學	TFDA-00269	ASTM	ASTM F1101-90(R2003)e1	2003	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)
17	Anesthesias 麻醉學	TFDA-00270	ASTM	ASTM G175-03	2003	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)

18	Anesthesias 麻醉學	TFDA-00271	ASTM	ASTM F1456-01	2001	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)
19	Anesthesias 麻醉學	TFDA-00405	ISO	ISO 10524-1: 2006	2006	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)
20	Anesthesias 麻醉學	TFDA-00406	ISO	ISO 10524-2: 2005	2005	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)
21	Anesthesias 麻醉學	TFDA-00407	ISO	ISO 10524-3: 2005	2005	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)
22	Anesthesias 麻醉學	TFDA-00408	ISO	ISO 10651-3:1997	1997	Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment	本標準已被廢除，請參考新標準。(ISO 80601-2-84:2020)
23	Anesthesias 麻醉學	TFDA-00411	ISO	ISO 21647: 2004/Cor 1:2005	2005	Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors-Technical Corrigendum 1	本標準已廢除，請參考新標準。(ISO 80601-2-55:2011)
24	Anesthesias 麻醉學	TFDA-00445	ISO	ISO 18779:2005	2005	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)
25	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
26	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

27	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
28	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
29	Anesthesias 麻醉學	TFDA-00694	ISO	ISO 5360:2006	2006	Anaesthetic vaporizers -- Agent-specific filling systems	本標準已改版，請參考新版本標準。(ISO 5360:2016)
30	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
31	Anesthesias 麻醉學	TFDA-01154	ASTM	ASTM G175 - 03(R2011)	2011	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)
32	Anesthesias 麻醉學	TFDA-01159	EN	EN 13544-1:2007+A1:2009	2010	Respiratory therapy equipment - Part 1: Nebulizing systems and their components - Incorporates Amendment A1: 2009	原採認標準已廢除，請參考取代標準。(EN ISO 27427 : 2019)
33	Anesthesias 麻醉學	TFDA-01160	IEC	IEC 60601-2-13:2009	2009	Medical electrical equipment – Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems - Edition 3.1; Consolidated Reprint	本標準已被廢除，請參考新標準。(ISO 80601-2-13:2011 + AMD 1:2015)
34	Anesthesias 麻醉學	TFDA-01161	IEC	IEC 60601-2-49:2011	2011	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)
35	Anesthesias 麻醉學	TFDA-01162	ISO	ISO 10079-1:1999	1999	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)
36	Anesthesias 麻醉	TFDA-01163	ISO	ISO 10079-2:1999	1999	Medical suction equipment - Part 2: Manually powered	本標準已改版，請參考新版

	學					suction equipment	本標準。(ISO 10079-2:2014)
37	Anesthesias 麻醉學	TFDA-01164	ISO	ISO 10079-3:1999	1999	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)
38	Anesthesias 麻醉學	TFDA-01166	ISO	ISO 14408:2005	2005	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)
39	Anesthesias 麻醉學	TFDA-01169	ISO	ISO 23747:2007	2007	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)
40	Anesthesias 麻醉學	TFDA-01171	ISO	ISO 5360:2012	2012	Anaesthetic vaporizers -- Agent-specific filling systems	本標準已改版，請參考新版本標準。(ISO 5360:2016)
41	Anesthesias 麻醉學	TFDA-01172	ISO	ISO 5361:2012	2012	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)
42	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)
43	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)
44	Anesthesias 麻醉學	TFDA-01176	ISO	ISO 80601-2-55:2011	2011	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)
45	Anesthesias 麻醉學	TFDA-01177	ISO	ISO 8359:1996/Amd 1:2012	2012	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)

衛生福利部食品藥物管理署歷年廢除或改版之醫療器材標準清單

46	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)
47	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)
48	Anesthesias 麻醉學	TFDA-01464	ISO	ISO 7376:2009	2009	Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation	本標準已改版，請參考新版本標準。(ISO 7376:2020)
49	Anesthesias 麻醉學	TFDA-01465	ISO	ISO 80369-7:2016	2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	本標準已改版，請參考新版本標準。(ISO 80369-7:2021)
50	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)
51	Anesthesias 麻醉學	TFDA-01467	ISO	ISO 80601-2-67:2014	2014	Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	本標準已改版，請參考新版本標準。(ISO 80601-2-67:2020)
52	Anesthesias 麻醉學	TFDA-01468	ISO	ISO 80601-2-69:2014	2014	Medical electrical equipment — Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment	本標準已改版，請參考新版本標準。(ISO 80601-2-69:2020)
53	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)
54	Anesthesias 麻醉學	TFDA-01764	IEC	IEC 80601-2-13:2018	2018	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of	本標準已改版，請參考新版本標準。(ISO

						an anaesthetic workstation	80601-2-13:2011/Amd 2:2018)
55	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)
56	Anesthesias 麻醉學	TFDA-01772	ISO	ISO 80601-2-70:2015	2015	Medical electrical equipment — Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment	本標準已改版，請參考新版本標準。(ISO 80601-2-70:2020)
57	Biocompatibility 生物相容性	TFDA-00006	ISO	ISO 10993-1：2003	2003	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)
58	Biocompatibility 生物相容性	TFDA-00007	ISO	ISO 10993-10：2002	2002	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)
59	Biocompatibility 生物相容性	TFDA-00008	ISO	ISO 10993-11：1993	1993	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)
60	Biocompatibility 生物相容性	TFDA-00009	ISO	ISO 10993-12：2002	2002	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)
61	Biocompatibility 生物相容性	TFDA-00010	ISO	ISO 10993-5：1999	1999	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)
62	Biocompatibility 生物相容性	TFDA-00011	ISO	ISO 10993-6：1994	1994	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)
63	Biocompatibility 生物相容性	TFDA-00012	ISO	ISO 10993-7：1995	1995	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)
64	Biocompatibility 生物相容性	TFDA-00016	ISO	ISO 10993-2:1992	1992	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)
65	Biocompatibility 生物相容性	TFDA-00018	ISO	ISO 10993-4:2002	2002	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)
66	Biocompatibility 生物相容性	TFDA-00019	ISO	ISO 10993-9:1999	1999	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)
67	Biocompatibility 生物相容性	TFDA-00020	ISO	ISO 10993-13:1998	1998	Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric	本標準已改版，請參考新版本標準。(ISO 10993-13:2010)
68	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)
69	Biocompatibility 生物相容性	TFDA-00023	ISO	ISO 10993-16:1997	1997	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)
70	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)
71	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)
72	Biocompatibility	TFDA-00514	ISO	ISO 10993-3:2003	2003	Biological evaluation of medical devices -- Part 3: Tests for	本標準已改版，請參考新版

	生物相容性					genotoxicity, carcinogenicity and reproductive toxicity	本標準。(ISO 10993-3:2014)
73	Biocompatibility 生物相容性	TFDA-00515	ISO	ISO 10993-4:2002/Amd 1:2006	2006	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)
74	Biocompatibility 生物相容性	TFDA-00516	ISO	ISO 10993-6:2007	2007	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)
75	Biocompatibility 生物相容性	TFDA-00517	ISO	ISO 10993-10:2002/Amd 1:2006	2006	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)
76	Biocompatibility 生物相容性	TFDA-00518	ISO	ISO 10993-11:2006	2006	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)
77	Biocompatibility 生物相容性	TFDA-00533	ISO	ISO/TS 20993:2006	2006	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)
78	Biocompatibility 生物相容性	TFDA-00668	ISO	ISO 10993-12:2007	2008	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)
79	Biocompatibility 生物相容性	TFDA-00726	ISO	ISO 10993-7：2008	2008	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)
80	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)
81	Biocompatibility 生物相容性	TFDA-00861	ISO	ISO 10993-16:2010	2010	Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and	本標準已改版，請參考新版本標準。(ISO 10993-16:2017)

						leachables	
82	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)
83	Biocompatibility 生物相容性	TFDA-01020	ASTM	ASTM F720-13	2013	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)
84	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)
85	Biocompatibility 生物相容性	TFDA-01022	ASTM	ASTM F750-87/(R)2012	2012	Standard Practice for Evaluating Acute Systemic Toxicity of Material Extracts by Systemic Injection in the Mouse	本標準已改版，請參考新版本標準。(ASTM F750 - 20)
86	Biocompatibility 生物相容性	TFDA-01023	ASTM	F813 - 07(2012)	2012	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	本標準已改版，請參考新版本標準。(ASTM F813 - 20)
87	Biocompatibility 生物相容性	TFDA-01024	ISO	ISO 10993-12:2012	2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	本標準已改版，請參考新版本標準。(ISO 10993-12:2021)
88	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)
89	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)
90	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)
91	Cardiovascular 心臟血管醫學	TFDA-00313	IEC	IEC 60601-2-31:1994	1998	Medical electrical equipment, Part 2: Particular requirements for the safety of external cardiac pacemakers with internal	本標準已改版，請參考新版本標準。(IEC

						power source	60601-2-31:2011 ed2.1 Consol. with am1)
92	Cardiovascular 心臟血管醫學	TFDA-00315	IEC	IEC 60601-2-25	1999	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)
93	Cardiovascular 心臟血管醫學	TFDA-00316	IEC	IEC 60601-2-47	2001	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)
94	Cardiovascular 心臟血管醫學	TFDA-00317	IEC	IEC 60601-2-4	2002	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)
95	Cardiovascular 心臟血管醫學	TFDA-00446	ISO	ISO 5840:2005	2005	Cardiovascular implants - Cardiac valve prostheses	本標準已改版，請參考新版本標準。(ISO 5840-1:2015)
96	Cardiovascular 心臟血管醫學	TFDA-00447	ISO	ISO 14708-2: 2005	2005	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)
97	Cardiovascular 心臟血管醫學	TFDA-00448	ISO	ISO 25539-1:2003/Amd 1:2005	2005	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)
98	Cardiovascular 心臟血管醫學	TFDA-00449	ISO	ISO 15676:2005	2005	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)
99	Cardiovascular	TFDA-00450	ISO	ISO 7198:1998	1998	Cardiovascular implants — Tubular vascular prostheses	本標準已改版，請參考新版

	心臟血管醫學						本標準。(ISO 7198:2017)
100	Cardiovascular 心臟血管醫學	TFDA-00451	ISO	ISO 7199:1996	1996	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)
101	Cardiovascular 心臟血管醫學	TFDA-00454	ISO	ISO 15674:2001	2001	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)
102	Cardiovascular 心臟血管醫學	TFDA-00455	ISO	ISO 15675:2001	2001	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)
103	Cardiovascular 心臟血管醫學	TFDA-00456	ISO	ISO 13960:2003	2003	Cardiovascular implants and artificial organs – Plasmafilters	本標準已改版，請參考新版本標準。(ISO 13960:2010)
104	Cardiovascular 心臟血管醫學	TFDA-00474	CEN	EN 14299:2004	2004	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)
105	Cardiovascular 心臟血管醫學	TFDA-00475	CEN	EN 12006-1:1999	1999	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)
106	Cardiovascular 心臟血管醫學	TFDA-00476	CEN	EN 12006-2:1998	1998	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)
107	Cardiovascular 心臟血管醫學	TFDA-00477	CEN	EN 12006-3:1998	1999	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)
108	Cardiovascular 心臟血管醫學	TFDA-00605	ASTM	ASTM F2081-01	2001	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。

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							(ASTM F2081-06/(R)2013)
109	Cardiovascular 心臟血管醫學	TFDA-00613	AAMI	AAMI DF80:2003	2003	Medical electrical equipment—Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)	本標準已廢除，請參考新標準。(IEC 60601-2-4:2010 ed3.0)
110	Cardiovascular 心臟血管醫學	TFDA-00614	AAMI	AAMI EC11:1991(R2001)	2001	Diagnostic electrocardiographic devices	本標準已廢除，請參考新標準。(IEC 60601-2-25:2011)
111	Cardiovascular 心臟血管醫學	TFDA-00615	AAMI	AAMI EC12:2000/(R)2005	2005	Disposable ECG electrodes	本標準已改版，請參考新版本標準。(AAMI EC12:2000/(R)2010)
112	Cardiovascular 心臟血管醫學	TFDA-00616	AAMI	AAMI EC53:1995/(R)2001	2001	ECG cables and leadwires	本標準已改版，請參考新版本標準。(AAMI EC53:2013)
113	Cardiovascular 心臟血管醫學	TFDA-00617	AAMI	AAMI EC57:1998/(R)2003	2003	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)
114	Cardiovascular 心臟血管醫學	TFDA-00619	IEC	IEC 60601-2-27:1994	1994	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)
115	Cardiovascular 心臟血管醫學	TFDA-00620	IEC	IEC 60601-2-30:1999	1999	Medical electrical equipment- Part 2-30: Particular requirements for safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment	本標準已廢除，請參考新標準。(IEC 80601-2-30:2013)
116	Cardiovascular 心臟血管醫學	TFDA-00621	IEC	IEC 60601-2-34:2000	2000	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)
117	Cardiovascular	TFDA-00625	ISO	ISO 5841-1:1989	1989	Cardiac Pacemakers - Part 1 : Implantable Pacemakers	本標準已廢除，請參考新標

	心臟血管醫學						準。(ISO 14708-2:2012)
118	Cardiovascular 心臟血管醫學	TFDA-00626	ISO	ISO 5841-2:2000	2000	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)
119	Cardiovascular 心臟血管醫學	TFDA-00627	ISO	ISO 5841-3:2000	2000	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)
120	Cardiovascular 心臟血管醫學	TFDA-00632	AAMI	AAMI SP10:2002/A1:2003	2002	Manual, electronic, or automated sphygmomanometers	本標準已廢除，請參考新標準。(ISO 81060-1:2007)
121	Cardiovascular 心臟血管醫學	TFDA-00704	AAMI	EC11:1991/(R)2007	1991	Diagnostic electrocardiographic devices	本標準已廢除，請參考新標準。(IEC 60601-2-25:2011)
122	Cardiovascular 心臟血管醫學	TFDA-00705	ASTM	F2081-06	2009	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)
123	Cardiovascular 心臟血管醫學	TFDA-00706	IEC	IEC 60601-2-27 Edition 2.0 (2005-08)	2005	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)
124	Cardiovascular 心臟血管醫學	TFDA-00707	IEC	IEC 60601-2-31 Edition 2.0 (2008-03)	2008	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)
125	Cardiovascular 心臟血管醫學	TFDA-00779	ISO	ISO 9919:2005	2005	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)
126	Cardiovascular	TFDA-00904	ISO	ISO 7199:2009	2009	Cardiovascular implants and artificial organs -- Blood-gas	本標準已改版，請參考新版

	心臟血管醫學					exchangers (oxygenators)	本標準。(ISO 7199:2016)
127	Cardiovascular 心臟血管醫學	TFDA-00905	ISO	ISO 15674:2009	2009	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)
128	Cardiovascular 心臟血管醫學	TFDA-00906	ISO	ISO 15675:2009	2009	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)
129	Cardiovascular 心臟血管醫學	TFDA-00908	AAMI	EC53:1995/(R)2008	2008	ECG cables and leadwires	本標準已改版，請參考新版本標準。(AAMI EC53:2013)
130	Cardiovascular 心臟血管醫學	TFDA-00909	AAMI	EC57:1998/(R)2008	2008	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)
131	Cardiovascular 心臟血管醫學	TFDA-00910	ISO	ANSI/AAMI/ISO 81060-2:2009	2009	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)
132	Cardiovascular 心臟血管醫學	TFDA-00976	CEN	EN 1060-1:1995	1995	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)
133	Cardiovascular 心臟血管醫學	TFDA-00977	CEN	EN 1060-3:1997	1997	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)
134	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))
135	Cardiovascular 心臟血管醫學	TFDA-01179	AAMI	AAMI EC53:2013	2013	ECG trunk cables and patient leadwires	本標準已改版，請參考新版本標準。(AAMI EC53:2013(R2020))

136	Cardiovascular 心臟血管醫學	TFDA-01180	AAMI	AAMI EC57:2012	2012	Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms	本標準已改版，請參考新版本標準。(ANSI/AAMI EC57:2012 (R2020))
137	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)
138	Cardiovascular 心臟血管醫學	TFDA-01183	AAMI	IEC 60601-2-25:2011	2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.	本標準已改版，請參考新版本標準。(IEC 60601-2-25:2011(R2016))
139	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))
140	Cardiovascular 心臟血管醫學	TFDA-01185	ASTM	ASTM F138- 00	2000	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 F138-13)
141	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))
142	Cardiovascular 心臟血管醫學	TFDA-01187	ASTM	ASTM F2004 - 05(R2010)	2010	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)
143	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
144	Cardiovascular	TFDA-01189	ASTM	ASTM F2079-09	2009	Standard Test Method for Measuring Intrinsic Elastic Recoil	本標準已改版，請參考新版

	心臟血管醫學					of Balloon Expandable Stents	本標準。(ASTM F2079 - 09(2017))
145	Cardiovascular 心臟血管醫學	TFDA-01190	ASTM	ASTM F2082 - 06	2006	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)
146	Cardiovascular 心臟血管醫學	TFDA-01191	ASTM	ASTM F2129 - 08	2008	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)
147	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))
148	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))
149	Cardiovascular 心臟血管醫學	TFDA-01194	ASTM	ASTM G71-81/(R)2009	2009	Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes	本標準已改版，請參考新版本標準。(ASTM G71 - 81(2019))
150	Cardiovascular 心臟血管醫學	TFDA-01195	CEN	EN 1060-3:1997+A2:2009	2009	Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems	本標準已廢除，無取代標準。
151	Cardiovascular 心臟血管醫學	TFDA-01196	CEN	EN 12006-2:1998+A1:2009	2009	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2:Vascular prostheses including cardiac valve conduits	本標準已被廢除，請參考新標準。(ISO 7198:2017)
152	Cardiovascular	TFDA-01197	CEN	EN ISO 5840:2009	2009	Cardiovascular implants - Cardiac valve prostheses	本標準已改版，請參考新版

	心臟血管醫學						本標準。(ISO 5840-1, -2, -3)
153	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
154	Cardiovascular 心臟血管醫學	TFDA-01201	IEC	IEC 60601-2-27:2011 ed3.0	2011	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)
155	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)
156	Cardiovascular 心臟血管醫學	TFDA-01204	IEC	IEC 60601-2-4:2010 ed3.0	2010	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	本標準已改版，請參考新版本標準。(IEC 60601-2-4:2018)
157	Cardiovascular 心臟血管醫學	TFDA-01206	IEC	IEC 80601-2-30:2013	2013	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)
158	Cardiovascular 心臟血管醫學	TFDA-01207	IEC	IEC 80601-2-61:2012	2011	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)
159	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)
160	Cardiovascular	TFDA-01212	ISO	ISO 25539-1:2009	2009	Cardiovascular implants - Endovascular devices - Part 1:	本標準已改版，請參考新版

	心臟血管醫學					Endovascular prostheses	本標準。(ISO 25539-1:2017)
161	Cardiovascular 心臟血管醫學	TFDA-01213	ISO	ISO 25539-2:2012	2012	Cardiovascular implants — Endovascular devices — Part 2: Vascular stents	本標準已改版，請參考新版本標準。(ISO 25539-2:2020)
162	Cardiovascular 心臟血管醫學	TFDA-01216	ISO	ISO 7199:2009/Amd 1:2012	2012	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)
163	Cardiovascular 心臟血管醫學	TFDA-01217	ISO	ISO 80601-2-61:2011	2011	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)
164	Cardiovascular 心臟血管醫學	TFDA-01221	OIML	OIML D11:2004	2004	General requirements for electronic measuring instruments	本標準已改版，請參考新版本標準。(OIML D11 (2013))
165	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)
166	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)
167	Cardiovascular 心臟血管醫學	TFDA-01479	ASTM	ASTM F2129-15	2015	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 F2129-17)
168	Cardiovascular 心臟血管醫學	TFDA-01480	ASTM	ASTM F2942-13	2013	Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents	本標準已改版，請參考新版本標準。(ASTM F2942 - 19)
169	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)
170	Cardiovascular	TFDA-01484	ISO	ISO 15675:2016	2016	Cardiovascular implants and artificial organs -	本標準已改版，請參考新版

	心臟血管醫學					Cardiopulmonary bypass systems - Arterial blood line filters	本標準。(ISO 15675:2016/AMD 1:2020)
171	Cardiovascular 心臟血管醫學	TFDA-01487	ISO	ISO 5840-1:2015	2015	Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements	本標準已改版，請參考新版本標準。(ISO 5840-1:2021)
172	Cardiovascular 心臟血管醫學	TFDA-01488	ISO	ISO 5840-2:2015	2015	Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes	本標準已改版，請參考新版本標準。(ISO 5840-2:2021)
173	Cardiovascular 心臟血管醫學	TFDA-01489	ISO	ISO 5840-3:2013	2013	Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques	本標準已改版，請參考新版本標準。(ISO 5840-3:2021)
174	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)
175	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)
176	Cardiovascular 心臟血管醫學	TFDA-01876	AAMI	AAMI EC12:2000/(R2015)	2015	Disposable ECG electrodes	本標準已改版，請參考新版本標準。(ANSI/AAMI EC12:2000 (R2020))
177	Cardiovascular 心臟血管醫學	TFDA-01882	ASTM	ASTM F746 - 04(2014)	2014	Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	本標準已改版，請參考新版本標準。(ASTM F746 - 04(2021))
178	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00057	ISO	ISO 13294:1997	1997	Dental Handpieces - Dental Air-Motors	本標準已廢除，請參考新標準。(ISO 14457:2012)
179	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00058	ISO	ISO 3336:1993	1993	Dentistry - Synthetic Polymer Teeth	本標準已改版，請參考新版本標準。(ISO 22112:2005)

180	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00059	ISO	ISO 4049:2000	2000	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)
181	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00060	ISO	ISO 7494:1996	1996	Dental Units	本標準已廢除，請參考新標準。(ISO 7494-1:2011)
182	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00061	ISO	ISO 7494-2:2003	2003	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)
183	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00062	ISO	ISO 7785-1:1997	1997	Part 1: High-Speed Air Turbine Handpieces	本標準已廢除，請參考新標準。(ISO 14457:2012)
184	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00063	ISO	ISO 7785-2:1995	1995	Part 2: Straight and Geared Angle Handpieces	本標準已廢除，請參考新標準。(ISO 14457:2012)
185	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00064	ISO	ISO 9168:1991	1991	Dental Handpieces - Hose Connectors	本標準已改版，請參考新版本標準。(ISO 9168:2009)
186	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00240	ISO	ISO 1562:1993	1993	Dental Casting Gold Alloys	本標準已廢除，請參考新標準。(ISO 22674:2016)
187	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00241	ISO	ISO 1563:1990	1990	Dental Alginate Impression Material	本標準已廢除，請參考新標準。(ISO 21563:2013)
188	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00242	ISO	ISO 1564:1995	1995	Dental Aqueous Impression Materials Based on Agar	本標準已廢除，請參考新標準。(ISO 21563:2013)
189	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00243	ISO	ISO 3107:1988	1988	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)
190	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00244	ISO	ISO 6871-1:1994	1994	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)
191	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00245	ISO	ISO 6871-2:1994	1994	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)

192	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00246	ISO	ISO 6872:1995+A1:1997	1998	Dental Ceramic	本標準已改版，請參考新版本標準。(ISO 6872:2015)
193	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00247	ISO	ISO 6874:1988	1988	Dental Resin-Based Pit and Fissue Sealants	本標準已改版，請參考新版本標準。(ISO 6874:2015)
194	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00248	ISO	ISO 6876:2001	2001	Dental Root Canal Sealing Materials	本標準已改版，請參考新版本標準。(ISO 6876:2012)
195	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00249	ISO	ISO 6877:1995	1995	Dental Root-Canal Obturating Points	本標準已改版，請參考新版本標準。(ISO 6877:2006)
196	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00250	ISO	ISO 10477:1996	2001	Dentistry - Polymer-Based Crown and Bridge Materials	本標準已改版，請參考新版本標準。(ISO 10477:2004)
197	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00251	ISO	ISO 11498:1997	1997	Dental Handpieces: Dental Low Voltage Electrical Motors	本標準已廢除，請參考新標準。(ISO 14457:2012)
198	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00252	ISO	ISO 13294:1997	1997	Dental Handpieces - Dental Air-Motors	本標準已廢除，請參考新標準。(ISO 14457:2012)
199	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00253	ISO	ISO 8891:2000	1998	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)
200	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00254	ISO	ISO 9693:1999	1999	Metal-Ceramic Dental Restorative Systems	本標準已改版，請參考新版本標準。(ISO 9693-1:2012)
201	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00255	ISO	ISO 9917-2:1998	1998	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)
202	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00256	ISO	ISO 13716:1999	1999	Dentistry - Reversible-Irreversible Hydrocolloid Impression Material Systems	本標準已廢除，請參考新標準。(ISO 21563:2013)
203	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00257	ISO	ISO 9917-1:2003	2002	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)

204	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00258	ISO	ISO 10139-1:1991	1991	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)
205	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00259	ISO	ISO 10139-2:1999	1999	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)
206	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00260	ISO	ISO 7494-1:2004	2004	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)
207	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)
208	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00375	CEN	EN 1639:1996	1996	Dentistry - Medical devices for dentistry - Instruments	本標準已改版，請參考新版本標準。(EN 1639:2009)
209	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00376	CEN	EN 1640:1996	1996	Dentistry - Medical devices for dentistry - Equipment	本標準已改版，請參考新版本標準。(EN 1640:2009)
210	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00377	CEN	EN 1641:1996	1996	Dentistry - Medical devices for dentistry - Materials	本標準已改版，請參考新版本標準。(EN 1641:2009)
211	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00378	CEN	EN 1642:1996	1996	Dentistry - Medical devices for dentistry - Dental implants	本標準已改版，請參考新版本標準。(EN 1642:2011)
212	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00379	ISO	ISO 6360-1: 2004	2004	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)
213	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00380	ISO	ISO 6360-2: 2004	2004	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)

214	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00386	ISO	ISO 13397-2: 2005	2005	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)
215	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00389	ISO	ISO 15854:2005	2005	Dentistry – Casting and baseplate waxes	本標準已改版，請參考新版本標準。(ISO 15854:2021)
216	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00390	ANSI	ASA S3.6-2004	2004	Specification for Audiometers	本標準已改版，請參考新版本標準。(ASA S3.6 (2010))
217	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00391	ANSI	ASA S3.22:2003	2003	Specification of Hearing Aid Characteristics	本標準已改版，請參考新版本標準。(ASA S3.22 (2014))
218	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00392	ISO	ISO 7405:1997	1997	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)
219	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00393	ISO	ISO 3107:2004	2006	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)
220	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00680	CEN	EN 1639:2004	2004	Dentistry - Medical devices for dentistry - Instruments	本標準已改版，請參考新版本標準。(EN 1639:2009)
221	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00681	CEN	EN 1640:2004	2004	Dentistry - Medical devices for dentistry - Equipment	本標準已改版，請參考新版本標準。(EN 1640:2009)
222	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00682	CEN	EN 1641:2004	2004	Dentistry - Medical devices for dentistry - Materials	本標準已改版，請參考新版本標準。(EN 1641:2009)
223	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00683	CEN	EN 1642:2004	2004	Dentistry - Medical devices for dentistry - Dental implants	本標準已改版，請參考新版本標準。(EN 1642:2011)
224	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00684	ISO	ISO 10139-1:2005 & ISO	2006	Dentistry - Soft lining materials for removable dentures - Part 1: Materials for short-term use Technical Corrigendum	本標準已改版，請參考新版本標準。(ISO 10139-1: 2018)

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225	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00685	ISO	ISO 10477:2004	2004	Dentistry -- Polymer-based crown and bridge materials	本標準已改版，請參考新版本標準。(ISO 10477:2018)
226	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00686	ISO	ISO 6874:2005	2005	Dentistry -- Polymer-based pit and fissure sealants	本標準已改版，請參考新版本標準。(ISO 6874:2015)
227	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00688	ISO	ISO 22674:2006	2006	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)
228	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00689	ISO	ISO 9693:1999/Amd 1:2005	2005	Metal-ceramic dental restorative systems.	本標準已被廢除，請參考新標準。(ISO 9693-1:2012)
229	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00871	ISO	ISO 22112:2005	2005	Dentistry -- Artificial teeth for dental prostheses	本標準已改版，請參考新版本標準。(ISO 22112:2107)
230	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)
231	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00874	ISO	ISO 6872:2008	2008	Dentistry -- Ceramic materials	本標準已改版，請參考新版本標準。(ISO 6872:2015)
232	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00875	ISO	ISO 9917-2:2010	2010	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)
233	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00876	ISO	ISO 10139-2:2009	2009	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)
234	Dental/ENT 牙科學/耳鼻喉科學	TFDA-00877	ISO	ISO 7405:2008	2008	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)
235	Dental/ENT 牙科	TFDA-00879	ASA	ANSI/ASA	2009	Specification of Hearing Aid Characteristics	本標準已改版，請參考新版

	學/耳鼻喉科學			S3.22-2009			本標準。(ASA S3.22 (2014))
236	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
237	Dental/ENT 牙科學/耳鼻喉科學	TFDA-01228	CNS	CNS 15492	2012	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。
238	Dental/ENT 牙科學/耳鼻喉科學	TFDA-01230	ISO	ISO 14457:2012	2012	Dentistry -- Handpieces and motors	本標準已改版，請參考新版本標準。(ISO 14457:2017)
239	Dental/ENT 牙科學/耳鼻喉科學	TFDA-01231	ISO	ISO 14801:2007	2007	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)
240	Dental/ENT 牙科學/耳鼻喉科學	TFDA-01237	ISO	ISO 7494-1:2011	2011	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)
241	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 performance of dental equipment	本標準已改版，請參考新版本標準。(IEC 80601-2-60:2019)
242	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)
243	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))
244	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)

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245	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)
246	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)
247	Dental/ENT 牙科學/耳鼻喉科學	TFDA-01790	ISO	ISO 10477:2018	2018	Dentistry -- Polymer-based crown and bridge materials	本標準已改版，請參考新版本標準。(ISO 10477:2020)
248	Dental/ENT 牙科學/耳鼻喉科學	TFDA-01963	ISO	ISO 17730:2014	2014	Dentistry - Fluoride varnishes	本標準已改版，請參考新版本標準。(ISO 17730:2020)
249	General I (QS/RM) 通用(品質管理系統/風險管理)	TFDA-00087	IEC	IEC 60812:1985	1985	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)
250	General I (QS/RM) 通用(品質管理系統/風險管理)	TFDA-00089	ISO	ISO 14971:2000	2000	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)
251	General I (QS/RM) 通用(品質管理系統/風險管理)	TFDA-00285	ISO	ISO 14155-1	2003	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)
252	General I (QS/RM) 通用(品質管理系統/	TFDA-00286	ISO	ISO 14155-2	2003	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)

	風險管理)						
253	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-00432	ISO	ISO/TR 16142	2006	Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices	本標準已被廢除，請參考新標準。(ISO 16142-1:2016)
254	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	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)
255	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
256	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)
257	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-00958	AAMI	AAMI HE75:2009	2009	Human factors engineering - Design of medical devices	本標準已改版，請參考新版本標準。(AAMI HE75:2009(R2018))
258	General I (QS/RM) 通用 (品質管理系統/	TFDA-01012	IEC	IEC 62366:2007	2007	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)

	風險管理)						
259	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-01013	ISO	ISO 14155:2011/Cor1:2011	2011	Clinical investigation of medical devices for human subjects -- Good clinical practice	本標準已改版，請參考新版本標準。(ISO 14155:2020)
260	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-01014	ISO	ISO 15223-1:2012	2012	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)
261	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)
262	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-01505	AAMI	AAMI TIR69:2017	2017	Risk management of radio-frequency wireless coexistence for medical devices and systems	本標準已改版，請參考新版本標準。(AAMI TIR69:2017(R2020))
263	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
264	General I (QS/RM) 通用 (品質管理系統/	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)

	風險管理)						
265	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-01512	ISO	ISO 16061:2015	2015	Instruments for use in association with non-active surgical implants — General requirements	本標準已改版，請參考新版本標準。(ISO 16061:2021)
266	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)
267	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)
268	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-01518	ISO	ISO/TS 19218-1/Amd1:2013	2013	Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes AMENDMENT 1 - First Edition	本標準已廢除，無取代標準。
269	General I (QS/RM) 通用 (品質管理系統/風險管理)	TFDA-01797	AAMI	AAMI TIR36:2007	2007	Validation of software for regulated processes	本標準已廢除，無取代標準。
270	General Plastic Surgery/General Hospital 一般及	TFDA-00117	ISO	ISO 10555-1:1995, A1: 1999	1999	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)

	整形外科手術/一般醫院及個人使用裝置						
271	General 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-00118	ISO	ISO 10555-3:1996, Cor1:2002	2002	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)
272	General 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	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)
273	General 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-00120	ISO	ISO 7886-1:1993	1995	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)
274	General Plastic Surgery/General Hospital 一般及	TFDA-00121	ISO	ISO 7886-2:1996	1996	Sterile Hypodermic Syringes for Single Use - Part 2: Syringes for use with Power-Driven Syringe Pumps	本標準已改版，請參考新版本標準。(ISO 7886-2:2020)

	整形外科手術/一般醫院及個人使用裝置						
275	General 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	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)
276	General 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	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)
277	General 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	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)
278	General Plastic Surgery/General Hospital 一般及	TFDA-00125	ISO	ISO 8536-4:2004	1998	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 8536-4:2010/Amd 1:2013)

	整形外科手術/一般醫院及個人使用裝置						
279	General 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	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)
280	General 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	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)
281	General 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	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。
282	General Plastic Surgery/General Hospital 一般及	TFDA-00288	ISO	ISO 595/2	1987	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。

	整形外科手術/一般醫院及個人使用裝置						
283	General 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	Sterile hypodermic needles for single use	本標準已改版，請參考新版本標準。(ISO 7864:2016)
284	General 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	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)
285	General 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	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)
286	General Plastic Surgery/General Hospital 一般及	TFDA-00292	ASTM	ASTM D5151-99	1999	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)

	整形外科手術/一般醫院及個人使用裝置						
287	General 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-00293	ISO	ISO 9626:1991	2001	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)
288	General 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	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)
289	General 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	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)
290	General Plastic Surgery/General Hospital 一般及	TFDA-00296	ASTM	ASTM D3578-01ae2	2002	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)

	整形外科手術/一般醫院及個人使用裝置						
291	General 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	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)
292	General 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-00299	ASTM	ASTM D3772-01	2002	Standard Specification for Natural Rubber Finger Cots	本標準已改版，請參考新版本標準。(ASTM D3772-15)
293	General 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	Standard Performance and Safety Specification for Cryosurgical Medical Instruments	本標準已廢除，無取代標準。
294	General Plastic Surgery/General Hospital 一般及	TFDA-00301	ASTM	ASTM F754-00	2000	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)

	整形外科手術/一般醫院及個人使用裝置						
295	General 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	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)
296	General 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	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)
297	General 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	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)
298	General Plastic Surgery/General Hospital 一般及	TFDA-00305	ISO	ISO 11608-3:2000	2000	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)

	整形外科手術/一般醫院及個人使用裝置						
299	General 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)
300	General 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)
301	General 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-00308	ISO	ISO 1135-4:1998	1998	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)
302	General Plastic Surgery/General Hospital 一般及	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

	整形外科手術/一般醫院及個人使用裝置						
303	General 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
304	General 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 Compatibility-Requirements and Tests (IDE IEC 60601-1-2)	原採認標準已廢除
305	General 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
306	General Plastic Surgery/General Hospital 一般及	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)

	整形外科手術/一般醫院及個人使用裝置						
307	General 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)
308	General 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)
309	General 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)
310	General Plastic Surgery/General Hospital 一般及	TFDA-00465	ISO	ISO 8362-1:2003	2003	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)

	整形外科手術/一般醫院及個人使用裝置						
311	General 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-00466	ISO	ISO 8362-2:1988	1988	Injection containers for injectables 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)
312	General 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	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)
313	General 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	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)
314	General Plastic Surgery/General Hospital 一般及	TFDA-00470	ISO	ISO 8362-6:1992	1992	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)

	整形外科手術/一般醫院及個人使用裝置						
315	General 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	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)
316	General 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	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)
317	General 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
318	General Plastic Surgery/General Hospital 一般及	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

	整形外科手術/一般醫院及個人使用裝置						
319	General 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	醫療用輸液設備一第五部份：量管型輸液套	原採認標準已廢除
320	General 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	醫療用輸液設備一第六部份：點滴瓶之凍晶乾燥瓶塞	原採認標準已廢除
321	General 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	醫療用輸液設備一第七部份：鋁一塑膠組合成之點滴瓶蓋	原採認標準已廢除
322	General Plastic Surgery/General Hospital 一般及	TFDA-00598	ISO	ISO 15883-1:2006	2006	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)

	整形外科手術/一般醫院及個人使用裝置						
323	General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	TFDA-00601	ISO	ISO/TS 15883-5:2005	2005	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	本標準已改版，請參考新版本標準。(ISO 15883-5:2021)
324	General 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	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)
325	General 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	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)
326	General Plastic Surgery/General Hospital 一般及	TFDA-00604	ASTM	ASTM E1965-98 (R2003)	2003	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)

	整形外科手術/一般醫院及個人使用裝置						
327	General 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	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)
328	General 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	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)
329	General 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	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)
330	General Plastic Surgery/General Hospital 一般及	TFDA-00611	AAMI	AAMI BF7:1989(R2002)	2002	Blood transfusion micro-filters	本標準已改版，請參考新版本標準。(AAMI BF7:2012)

	整形外科手術/一般醫院及個人使用裝置						
331	General 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	Blood pressure transducers	本標準已改版，請參考新版本標準。(AAMI BP22:1994(R2011))
332	General 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	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)
333	General 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	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)
334	General Plastic Surgery/General Hospital 一般及	TFDA-00624	ISO	ISO 594-2:1998	1998	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)

	整形外科手術/一般醫院及個人使用裝置						
335	General 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-00629	ISO	ISO 8537:1991/Amd.1:2000	2000	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)
336	General 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	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)
337	General 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	Infant incubators	本標準已改版，請參考新版本標準。(II36:2004)
338	General Plastic Surgery/General Hospital 一般及	TFDA-00643	ISO	ISO 10555-5:1996/Amd.1:1999, Cor.1:2002	2002	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)

	整形外科手術/一般醫院及個人使用裝置						
339	General 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	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)
340	General 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-00711	AAMI	BF7:1989/(R)2007	1989	Blood transfusion micro-filters	本標準已改版，請參考新版本標準。(AAMI BF7:2012)
341	General 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	Blood pressure transducers	本標準已改版，請參考新版本標準。(AAMI BP22:1994(R2011))
342	General Plastic Surgery/General Hospital 一般及	TFDA-00713	ASTM	D3772-01(R2005)	2005	Standard Specification for Natural Rubber Finger Cots	本標準已改版，請參考新版本標準。(ASTM D3772-15)

	整形外科手術/一般醫院及個人使用裝置						
343	General 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	ASTM D5151-06	本標準已改版，請參考新版本標準。(ASTM D5151-06/(R)2011)
344	General 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	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)
345	General 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	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)
346	General Plastic Surgery/General Hospital 一般及	TFDA-00717	ASTM	F1671-07	2007	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a	本標準已改版，請參考新版本標準。(ASTM F1671/F1671M-13)

	整形外科手術/一般醫院及個人使用裝置					Test System	
347	General 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))
348	General 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	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)
349	General 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	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)
350	General Plastic Surgery/General Hospital 一般及	TFDA-00721	ISO	ISO 8536-4:2007	2007	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)

	整形外科手術/一般醫院及個人使用裝置						
351	General 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-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))
352	General 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	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)
353	General 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	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)
354	General Plastic Surgery/General Hospital 一般及	TFDA-00922	IEC	IEC 60601-2-2 ed5.0 : 2009	2009	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency	本標準已改版，請參考新版本標準。(IEC 60601-2-2:2009 + CORR 1:2014)

	整形外科手術/一般醫院及個人使用裝置					surgical accessories	
355	General 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))
356	General 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	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)
357	General 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	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)
358	General Plastic Surgery/General Hospital 一般及	TFDA-00926	ISO	ISO 8362-2:2008	2008	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)

	整形外科手術/一般醫院及個人使用裝置						
359	General 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	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)
360	General 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))
361	General 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))
362	General Plastic Surgery/General Hospital 一般及	TFDA-00931	ASTM	ASTM F1670-08	2008	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)

	整形外科手術/一般醫院及個人使用裝置						
363	General 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	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)
364	General 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-00979	CEN	EN 13795-1:2002	2002	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment —Part 1: General requirements for manufacturers, processors and products	本標準已改版，請參考新版本標準。(EN 13795:2011+A1:2013)
365	General 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	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)
366	General Plastic Surgery/General Hospital 一般及	TFDA-00981	CEN	EN 13795-3:2006	2006	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)

	整形外科手術/一般醫院及個人使用裝置						
367	General 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	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)
368	General 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	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)
369	General 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)
370	General Plastic Surgery/General Hospital 一般及	TFDA-00985	CEN	EN 455-2:2000	2000	Medical gloves for single use —Part 2: Requirements and testing for physical properties	本標準已改版，請參考新版本標準。(EN 455-2:2015)

	整形外科手術/一般醫院及個人使用裝置						
371	General 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	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)
372	General 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	2005	Single-use sterile rubber surgical gloves -- Specification	本標準已改版，請參考新版本標準。(ISO 10282:2014)
373	General 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	2008	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)
374	General Plastic Surgery/General Hospital 一般及	TFDA-01254	IEC	IEC 80601-2-59:2008	2008	Medical electrical equipment -- Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature	本標準已改版，請參考新版本標準。(IEC 80601-2-59:2017)

	整形外科手術/一般醫院及個人使用裝置					screening	
375	General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	TFDA-01257	AAMI	ANSI/AAMI BF7:2012	2012	Blood transfusion micro-filters	本標準已廢除，無取代標準。
376	General 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-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 BP22:1994/(R2016))
377	General 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)
378	General Plastic Surgery/General Hospital 一般及	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)

	整形外科手術/一般醫院及個人使用裝置						
379	General 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)	2010	Standard Specification for Natural Rubber Finger Cots	本標準已改版，請參考新版本標準。(ASTM D3772-15)
380	General 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)
381	General 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))
382	General Plastic Surgery/General Hospital 一般及	TFDA-01265	ASTM	ASTM D6355-07/(R)2012	2012	Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves	本標準已改版，請參考新版本標準。(ASTM D6355 - 07(2017))

	整形外科手術/一般醫院及個人使用裝置						
383	General 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	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)
384	General 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))
385	General 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)	2010	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)
386	General Plastic Surgery/General Hospital 一般及	TFDA-01269	ASTM	ASTM D7161-05(R2010)	2010	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)

	整形外科手術/一般醫院及個人使用裝置						
387	General 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))
388	General 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	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)
389	General 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	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)
390	General Plastic Surgery/General Hospital 一般及	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)

	整形外科手術/一般醫院及個人使用裝置						
391	General 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)
392	General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	TFDA-01281	ASTM	ASTM F86-13	2013	Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	本標準已改版，請參考新版本標準。(ASTM F86 - 21)
393	General 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)
394	General Plastic Surgery/General Hospital 一般及	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,	原採認標準已廢除，請參考取代標準。(EN 13795-1, EN 13795-2)

	整形外科手術/一般醫院及個人使用裝置					test methods, performance requirements and performance levels	
395	General 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-01285	CEN	EN 455-2:2009+A2:2013	2013	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)
396	General 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	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)
397	General 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	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)
398	General Plastic Surgery/General Hospital 一般及	TFDA-01297	IEC	IEC 60601-2-50:2009+Corr1:2009	2009	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)

	整形外科手術/一般醫院及個人使用裝置						
399	General 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	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)
400	General 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-01299	IEC	IEC 80601-2-35:2009+Corr2:2015	2015	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use	本標準已改版，請參考新版本標準。(IEC 80601-2-35:2016)
401	General 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	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)
402	General Plastic Surgery/General Hospital 一般及	TFDA-01303	ISO	ISO 1135-4:2012	2012	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)

	整形外科手術/一般醫院及個人使用裝置						
403	General 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	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)
404	General 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	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)
405	General 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)
406	General Plastic Surgery/General Hospital 一般及	TFDA-01313	ISO	ISO 9626:1991/Amd 1:2001	2001	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)

	整形外科手術/一般醫院及個人使用裝置						
407	General 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))
408	General 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-01315	ASTM	ASTM D5250-06/(R)2011	2011	Standard Specification for Poly(vinyl chloride) Gloves for Medical Application	本標準已改版，請參考新版本標準。(ASTM D5250 - 19)
409	General 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
410	General Plastic Surgery/General Hospital 一般及	TFDA-01318	IEC	IEC 60601-2-20:2009 ed2.0	2009	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)

	整形外科手術/一般醫院及個人使用裝置						
411	General 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	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)
412	General 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)
413	General 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)
414	General Plastic Surgery/General Hospital 一般及	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)

	整形外科手術/一般醫院及個人使用裝置						
415	General 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-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)
416	General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	TFDA-01534	IEC	IEC 60601-2-20:2009+AMD1:2016	2016	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	本標準已改版，請參考新版本標準。(IEC 60601-2-20:2020)
417	General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	TFDA-01535	IEC	IEC 60601-2-21:2009+AMD1:2016	2016	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	本標準已改版，請參考新版本標準。(IEC 60601-2-21:2020)
418	General Plastic Surgery/General Hospital 一般及	TFDA-01537	IEC	IEC 60601-2-50:2009+AMD1:2016	2016	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	本標準已改版，請參考新版本標準。(IEC 60601-2-50:2020)

	整形外科手術/一般醫院及個人使用裝置						
419	General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	TFDA-01539	IEC	IEC 80601-2-35:2009+AMD1:2016	2016	Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use	本標準已改版，請參考新版本標準。(IEC 60601-2-35:2020)
420	General 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)
421	General 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-01798	ASTM	ASTM F1670/F1670M:2017	2017	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 - 17a)
422	General Plastic Surgery/General Hospital 一般及	TFDA-01801	IEC	IEC 60601-2-19:2009+AMD1:2016	2016	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	本標準已改版，請參考新版本標準。(IEC 60601-2-19:2020)

	整形外科手術/一般醫院及個人使用裝置						
423	General 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)
424	General 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)
425	General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	TFDA-01898	ISO	ISO 11193-1:2008/AMD 1:2012	2012	Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution	本標準已改版，請參考新版本標準。(ISO 11193-1:2020)
426	General Plastic Surgery/General Hospital 一般及	TFDA-01978	ASTM	ASTM D7169 - 20	2020	Standard Test Method for Boiling Point Distribution of Samples with Residues Such as Crude Oils and Atmospheric and Vacuum Residues by High Temperature Gas	本標準已改版，請參考新版本標準。(ASTM D7169 - 20e1)

	整形外科手術/一般醫院及個人使用裝置					Chromatography	
427	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00038	CEN	EN 13640:2002	2002	Stability Testing of In Vitro Diagnostic Reagents	本標準已廢除，請參考新標準。(ISO 23640:2011)
428	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00039	CLSI	NCCLS C28-A2:2000	2002	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)
429	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00040	CLSI	NCCLS EP10-A2:2002	2002	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)
430	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00041	CLSI	NCCLS EP12-A:2002	2002	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)
431	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00042	CLSI	NCCLS EP14-A:2001	2001	Evaluation of Matrix Effects; Approved Guideline	本標準已改版，請參考新版本標準。(EP14-A3)
432	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00043	CLSI	NCCLS EP15-A:2001	2001	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)
433	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00044	CLSI	NCCLS EP18-A:2002	2002	Quality Management for Unit-Use Testing; Approved Guideline	本標準已改版，請參考新版本標準。(EP18-A2)

434	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00045	CLSI	NCCLS EP5-A:1999	1999	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)
435	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00046	CLSI	NCCLS EP7-A:2002	2002	Interference Testing in Clinical Chemistry; Approved Guideline	本標準已改版，請參考新版本標準。(EP7-A2)
436	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00047	CLSI	NCCLS EP9-A2:2002	2002	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)
437	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00048	CLSI	NCCLS GP 10-A:1995	1995	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)
438	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00050	CLSI	NCCLS GP16-A2:2001	2001	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)
439	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00051	CLSI	NCCLS GP19-A2:2001	2003	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition	本標準已廢除，請參考新標準。(AUTO13-A2)
440	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00052	CLSI	NCCLS GP20-A:1996	2003	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)
441	In Vitro Diagnostics 體外	TFDA-00053	CLSI	NCCLS GP22-A:1999	1999	Continuous Quality Improvement: Essential Management Approaches; Approved Guideline	本標準已改版，請參考新版本標準。(GP22-A3)

	診斷醫療器材						
442	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00054	CLSI	NCCLS GP27-A:1999	1999	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)
443	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00055	CLSI	NCCLS NRSCL 8-A:1998	1998	Terminology and Definitions for use in NCCLS Documents; Approved Standard	本標準已廢除，無取代標準。
444	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00168	CLSI	I/LA18-A 1994	1994	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)
445	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00169	CLSI	MM3-A 1995	1995	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))
446	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00170	CLSI	C12-A	1994	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)
447	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00171	CLSI	C21-A	1992	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)
448	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00172	CLSI	C25-A	1997	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)
449	In Vitro Diagnostics 體外	TFDA-00173	CLSI	C27-A	1993	Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline	本標準已廢除，請參考新標準。(C46-A2)

	診斷醫療器材					(1993)	
450	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00174	CLSI	C30-A	1994	Ancillary (Bedside) Blood Glucose Testing	本標準已改版，請參考新版本標準。(POCT12-A3)
451	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00175	CLSI	C42-A	1996	Erythrocyte Protoporphyrin Testing; Approved Guideline (1996)	本標準已廢除，無取代標準。
452	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00176	CLSI	H10-A2	1995	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。
453	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00177	CLSI	H14-A2	1990	Devices for Collection of Skin Puncture Blood Specimens - Second Edition; Approved Guideline (1990)	本標準已廢除，無取代標準。
454	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00178	CLSI	H20-A	1992	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)
455	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00179	CLSI	H44-A	1997	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)
456	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00180	CLSI	H47-A	1996	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)
457	In Vitro Diagnostics 體外	TFDA-00181	CLSI	I/LA2-A	1996	Quality Assurance for the Indirect Immunoflurescence Test for Autoantibodies to Nuclear Antigen (IF-ANA); Approved	本標準已改版，請參考新版本標準。(ILA2-A2)

	診斷醫療器材					Guideline (1996)	
458	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00182	CLSI	I/LA6-A	1997	Detection and Quantitation of Rubella IGG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline (1997)	本標準已廢除，無取代標準。
459	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00183	CLSI	I/LA10-A	1996	Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline (1996)	本標準已廢除，無取代標準。
460	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00184	CLSI	I/LA17-A	1997	Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Neural Tube Defects; Approved Guideline (1997)	本標準已廢除，請參考新標準。(I/LA25-A2)
461	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00185	CLSI	I/LA19-A	1997	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。
462	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00186	CLSI	I/LA20-A	1997	Evaluation Methods and Analytical Performance Characteristics of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies of Defined Allergen Specificities; Approved Guideline (1997)	本標準已改版，請參考新版本標準。(CLSI I/LA20-ED3)
463	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00187	CLSI	H26-A	1996	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)
464	In Vitro Diagnostics 體外	TFDA-00189	CLSI	H42-A	1998	Clinical Application of Flow Cytometry: Quality Assurance and Immunophenotyping of Lymphocytes; Approved	本標準已改版，請參考新版本標準。(H42-A2)

	診斷醫療器材					Guideline	
465	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00190	CLSI	I/LA21-A	2002	Clinical Evaluation of Immunoassays; Approved Guideline	本標準已改版，請參考新版本標準。(ILA21-A2)
466	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00193	CLSI	M22-A2	1996	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)
467	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00194	CLSI	M23-A	1994	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline	本標準已改版，請參考新版本標準。(M23-A3)
468	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00195	CLSI	M28-A	1997	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)
469	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00196	CLSI	MM1-A	2000	Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline	本標準已改版，請參考新版本標準。(MM01-A3)
470	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00197	CLSI	C46-A	2001	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)
471	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00198	CLSI	H43-A	1998	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)
472	In Vitro Diagnostics 體外	TFDA-00199	CLSI	MM2-A	1995	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)

	診斷醫療器材						
473	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00200	ISO	ISO 15197	2003	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)
474	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00201	CLSI	DI1-A2	1992	Glossary and Guidelines for Immunodiagnostic Procedures, Reagents and Reference Materials-Second Edition	本標準已廢除，無取代標準。
475	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00202	CLSI	MM-5A	2003	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)
476	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00203	CLSI	C24-A2	1999	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))
477	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00204	CLSI	C29-A2	2000	Standardization of Sodium and Potassium Ion Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard (2000)	本標準已廢除，無取代標準。
478	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00205	CLSI	C31-A2	2001	Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline - Second Edition (2001)	本標準已廢除，無取代標準。
479	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00206	CLSI	DI02-A2	1993	Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials - Second Edition; Approved Guideline	本標準已廢除，無取代標準。
480	In Vitro Diagnostics 體外	TFDA-00207	CLSI	H1-A5	2003	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

	診斷醫療器材						(GP39-A6))
481	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00208	CLSI	H4-A4	1999	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)
482	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00209	CLSI	H07-A3	2000	Procedure for Determining Packed Cell Volume by the Microhematocrit Method - Second Edition; Approved Standard - Third Edition	本標準已廢除，無取代標準。
483	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00210	CLSI	H30-A2	2001	Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline Second Edition	本標準已廢除，無取代標準。
484	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
485	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00212	CLSI	LA01-A2	1994	Assessing the Quality of Radioimmunoassay Systems - Second Edition; Approved Guideline	本標準已廢除，無取代標準。
486	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00213	CLSI	M2-A8	2003	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)
487	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00214	CLSI	M7-A6	2003	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)
488	In Vitro Diagnostics 體外	TFDA-00215	CLSI	M11-A6	2004	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)

	診斷醫療器材						
489	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00216	CLSI	M24-A	2003	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)
490	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00218	CLSI	M27-A	1999	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)
491	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00220	CLSI	RS2-A	1998	The National Reference System for the Clinical Laboratory (NRSCL) Aspartate Aminotransferase (AST)	本標準已廢除，無取代標準。
492	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00221	CLSI	RS3-A	1987	The National Reference System for the Clinical Laboratory (NRSCL) Cholesterol	本標準已廢除，無取代標準。
493	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00222	CLSI	RS5-A2	1993	The National Reference System for the Clinical Laboratory (NRSCL) Total Protein	本標準已廢除，無取代標準。
494	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00223	CLSI	RS6-A	1989	The National Reference System for the Clinical Laboratory (NRSCL) Total Bilirubin	本標準已廢除，無取代標準。
495	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00224	CLSI	T/DM6-A	1997	Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997)	本標準已廢止
496	In Vitro Diagnostics 體外	TFDA-00318	CEN	EN 375:2001	2000	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)

	診斷醫療器材						
497	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)
498	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00322	CLSI	MM9-A	2004	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine	本標準已改版，請參考新版本標準。(MM09-A2)
499	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00323	CLSI	H21-A4	2003	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)
500	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00324	CLSI	I/LA23-A	2004	Assessing the Quality of Immunoassay Systems: Radioimmunoassays, and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guidelines	本標準已廢除，無取代標準。
501	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 professional use─Summary of regulatory requirements for information supplied by the manufacturer	原採認標準已廢除
502	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00326	CLSI	C3-A4	2006	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)
503	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00327	CLSI	C49-P	2006	Analysis of body fluids in clinical laboratory	本標準已改版，請參考新版本標準。(C49-A)
504	In Vitro	TFDA-00330	CLSI	MM10-P	2005	Genotyping for infectious diseases: Identification and	本標準已改版，請參考新版

	Diagnostics 體外診斷醫療器材					characterization	本標準。(MM10-A)
505	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00331	CLSI	MM11-P	2006	Molecular methods for bacterial strain typing	本標準已改版，請參考新版本標準。(MM11-A)
506	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00332	CLSI	MM12-A	2006	Diagnostic nucleic acid microarrays	本標準已廢除，無取代標準。
507	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00333	CLSI	C38-A	1997	Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline	本標準已廢除，無取代標準。
508	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00335	CLSI	C43-A	2002	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)
509	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00338	CLSI	H17-A	1998	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)
510	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00340	CLSI	MM4-A	1999	Quality Assurance for Immunocytochemistry; Approved Guideline	本標準已廢除，無取代標準。
511	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00341	CLSI	MM6-A	2003	Quantitative Molecular Methods for Infectious Diseases; Proposed Guideline	本標準已改版，請參考新版本標準。(MM06-A2)
512	In Vitro	TFDA-00342	CLSI	MM14-A	2001	Proficiency Testing (External Quality Assessment) for	本標準已改版，請參考新版

	Diagnostics 體外診斷醫療器材					Molecular Methods; Approved Guideline	本標準。(MM14-A2)
513	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00343	CLSI	POCT1-A	2005	Point-of-Care Connectivity; Approved Standard	本標準已改版，請參考新版本標準。(POCT1-A2)
514	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00480	ISO	ISO 22870:2006	2006	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
515	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00482	CLSI	POCT2-P	2007	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)
516	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00483	CLSI	POCT4-A2	2006	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)
517	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00484	CNS	CNS 15035:2006	1996	體外診斷系統－糖尿病管理時自我檢測用血糖監測系統之規定	本標準已廢止
518	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00486	ANSI	AST3-A	1999	Wellness Testing Using IVD Devices; Approved Guideline	本標準已廢除，無取代標準。
519	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00487	ANSI	AST4-A2	2005	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))

520	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00495	CLSI	C40-A	2001	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)
521	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00496	CLSI	EP06-A	2003	Evaluation of the Linearity of Quantitative Measurement Procedures	本標準已改版，請參考新版本標準。(CLSI EP06 Ed2)
522	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00497	CLSI	EP17-A	2004	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)
523	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00498	CLSI	EP21-A	2003	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)
524	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00499	CLSI	GP10-A	1995	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)
525	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00500	CLSI	M6-A	2003	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)
526	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00501	CLSI	M7-A7	2006	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)
527	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

528	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00504	CLSI	M23-A2	2001	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)
529	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00507	CLSI	M31-S1	2004	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)
530	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00508	CLSI	M31-A2	2002	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)
531	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
532	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00510	CLSI	M39-A	2002	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)
533	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00511	CLSI	M45-P	2005	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)
534	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00648	CLSI	M6-A2	2006	Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard - Second Edition	本標準已廢止
535	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00649	CLSI	C24-A3	2006	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)

536	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00656	CLSI	ILA2-A2	2006	Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods; Approved Guideline - Second Edition	本標準已廢止
537	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00657	CLSI	M11-A7	2007	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)
538	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00659	CLSI	MM3-A2	2006	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)
539	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00662	CLSI	EP14-A2	2005	Evaluation of Matrix Effects; Approved Guideline-Second Edition	本標準已改版，請參考新版本標準。(EP14-A3)
540	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00663	CLSI	EP15-A2	2006	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)
541	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00664	CLSI	EP5-A2	2004	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)
542	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00665	CLSI	GP22-A2	2004	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)
543	In Vitro Diagnostics 體外	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

	診斷醫療器材						
544	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00667	CLSI	GP20-A2	2003	Fine-Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline-Second Edition	本標準已廢除，無取代標準。
545	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00733	CLSI	H49-A	2004	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline	本標準已廢除，請參考新標準。(POCT14-A)
546	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00734	CLSI	C30-A2	2002	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)
547	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00830	CLSI	C28-A3	2008	How to Define and Determine Reference Intervals in the Clinical Laboratory	本標準已廢除，請參考新標準。(EP28-A3C)
548	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00831	CLSI	EP10-A3	2006	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)
549	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00833	CLSI	EP09-A2-IR	2010	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)
550	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00836	CLSI	H47-A2	2005	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)
551	In Vitro Diagnostics 體外	TFDA-00837	CLSI	I/LA25-A	2004	Maternal Serum Screening; Approved Standard	本標準已改版，請參考新版本標準。(I/LA25-A2)

	診斷醫療器材						
552	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00838	CLSI	I/LA20-A2	2009	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)
553	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00842	CLSI	MM01-A2	2006	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)
554	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00843	CLSI	MM02-A2	2002	Immunoglobin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline - Second Edition	本標準已廢除，無取代標準。
555	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00844	CLSI	H04-A6	2008	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)
556	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00845	CLSI	M02-A10	2009	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)
557	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00846	CLSI	M07-A8	2009	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)
558	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00847	CLSI	M27-A3	2008	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)
559	In Vitro	TFDA-00848	CLSI	C49-A	2007	Analysis of Body Fluids in Clinical Chemistry; Approved	本標準已改版，請參考新版

	Diagnostics 體外診斷醫療器材					Guideline	本標準。(C49)
560	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00853	CLSI	POCT02-A	2008	Implementation Guide of POCT01 for Health Care Providers; Approved Guideline	本標準已廢除，無取代標準。
561	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00854	CLSI	M31-A3	2008	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)
562	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00855	CLSI	M39-A3	2009	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)
563	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00856	CLSI	M45-A	2006	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)
564	In Vitro Diagnostics 體外診斷醫療器材	TFDA-00944	CLSI	I/LA30-A	2008	Immunoassay Interference by Endogenous Antibodies; Approved Guideline	本標準已廢除，無取代標準。
565	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
566	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)
567	In Vitro	TFDA-01118	CLSI	GP22-A3	2011	Quality Management System: Continual Improvement;	原採認標準已廢除

	Diagnostics 體外診斷醫療器材					Approved Guideline—Third Edition	
568	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)
569	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01126	CLSI	M45-A2	2010	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)
570	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01132	CLSI	POCT13-A2	2005	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)
571	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01133	CLSI	POCT14-A	2004	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline	本標準已改版，請參考新版本標準。(CLSI POCT14 : 2020)
572	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)
573	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01136	CLSI	VET01-S2	2013	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)
574	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01141	IEC	IEC 61010-1:2010+Corr1: 2010	2010	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)

575	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01142	IEC	IEC 61010-2-101:2002	2002	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)
576	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01143	IEC	IEC 61326-2-6:2012 ed2.0	2012	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment - Edition 2.0	本標準已改版，請參考新版本標準。(IEC 61326-2-6:2020)
577	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)
578	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)
579	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01455	CLSI	AUTO13-A2	2003	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline - Second Edition; Vol. 23; No. 4	本標準已廢除，無取代標準。
580	In Vitro Diagnostics 體外	TFDA-01566	CLSI	EP19	2015	A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures - Second	本標準已改版，請參考新版本標準。(CLSI EP19 : 2020)

	診斷醫療器材					Edition; Vol 35; No 10	
581	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 requirements	本標準已改版，請參考新版本標準。(IEC 61010-1:2010/AMD1:2016/COR1:2019)
582	In Vitro Diagnostics 體外診斷醫療器材	TFDA-01579	ISO	ISO/TS 17822-1:2014	2014	In vitro diagnostic test systems — Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens — Part 1: General requirements, terms and definitions	本標準已改版，請參考新版本標準。(ISO 17822:2020)
583	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)
584	Materials 材料	TFDA-00066	ISO	ISO 5832-1:1997	1997	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)
585	Materials 材料	TFDA-00067	ISO	ISO 5832-2:1999	1999	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)
586	Materials 材料	TFDA-00068	ISO	ISO 5832-3:1996	1996	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)
587	Materials 材料	TFDA-00069	ISO	ISO 5832-4:1996	1996	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)
588	Materials 材料	TFDA-00070	ISO	ISO 5832-5:1993	1993	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)
589	Materials 材料	TFDA-00072	ISO	ISO 5832-7:1994	1994	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)

590	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
591	Materials 材料	TFDA-00074	ISO	ISO 5832-9:1992	1992	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)
592	Materials 材料	TFDA-00075	ISO	ISO 5832-11:1994	1994	Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy	本標準已改版，請參考新版本標準。(ISO 5832-11:2014)
593	Materials 材料	TFDA-00076	ISO	ISO 5832-12:1996	1996	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)
594	Materials 材料	TFDA-00077	ISO	ISO 5834-1:1998	1998	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)
595	Materials 材料	TFDA-00078	ISO	ISO 5834-2:1998	1998	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)
596	Materials 材料	TFDA-00079	ISO	ISO 6474-1994	1994	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)
597	Materials 材料	TFDA-00261	ISO	ISO 14708-1: 2000	2000	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)
598	Materials 材料	TFDA-00395	ISO	ISO 5834-2: 2006	2006	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)
599	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
600	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

601	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
602	Materials 材料	TFDA-00880	ISO	ISO 5832-1:2007/Cor 1:2008	2008	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)
603	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)
604	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)
605	Materials 材料	TFDA-00951	AAMI	ST65:2000	2000	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)
606	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))
607	Materials 材料	TFDA-00953	ISO	ISO 139:2005	2005	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)
608	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)
609	Materials 材料	TFDA-01085	AATCC	AATCC 127-2008	2014	Water Resistance: Hydrostatic Pressure Test	本標準已改版，請參考新版本標準。(AATCC 127-2017)
610	Materials 材料	TFDA-01087	ASTM	ASTM F1091-12	2012	Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605)	本標準已改版，請參考新版本標準。(ASTM F1091 - 20)
611	Materials 材料	TFDA-01088	ASTM	ASTM F136-12a	2012	Standard Specification for Wrought	本標準已改版，請參考新版

						Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	本標準。(ASTM F136-13)
612	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)
613	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)
614	Materials 材料	TFDA-01092	ASTM	ASTM F2026-12	2012	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)
615	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))
616	Materials 材料	TFDA-01095	ASTM	ASTM F2459-12	2012	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)
617	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))
618	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)
619	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)

620	Materials 材料	TFDA-01581	ASTM	ASTM D3772-15	2015	Standard Specification for Industrial Rubber Finger Cots	本標準已改版，請參考新版本標準。(ASTM D3772 - 15(2021))
621	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)
622	Materials 材料	TFDA-01584	ASTM	ASTM F136-13	2013	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	本標準已改版，請參考新版本標準。(ASTM F136 - 13(2021)e1)
623	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))
624	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)
625	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)
626	Materials 材料	TFDA-01588	ASTM	ASTM F2224-09/(R)2014	2014	Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants	本標準已改版，請參考新版本標準。(ASTM F2224 - 09(2020))
627	Materials 材料	TFDA-01591	ASTM	ASTM F2565-13	2013	Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications	本標準已改版，請參考新版本標準。(ASTM F2565 - 21)
628	Materials 材料	TFDA-01592	ASTM	ASTM F2695-12	2012	Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol	本標準已改版，請參考新版本標準。(ASTM F2695 -

						(Vitamin E) and Fabricated Forms for Surgical Implant Applications	12(2020))
629	Materials 材料	TFDA-01593	ASTM	ASTM F2820-12	2012	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	本標準已改版，請參考新版本標準。(ASTM F2820 - 12(2021)e1)
630	Materials 材料	TFDA-01594	ASTM	ASTM F2971-13	2013	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing	本標準已改版，請參考新版本標準。(ASTM F2971 - 13(2021))
631	Materials 材料	TFDA-01805	ASTM	ASTM D412-16	2016	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(2021))
632	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)
633	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)
634	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)
635	Materials 材料	TFDA-01904	ASTM	ASTM F2393 - 12(2016)	2016	Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications	本標準已改版，請參考新版本標準。(ASTM F2393 - 12(2020))
636	Materials 材料	TFDA-01905	ASTM	ASTM F621 - 12(2017)	2017	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(2021)e1)

637	Materials 材料	TFDA-01906	ASTM	ASTM F1581 - 08(2016)	2016	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(2020))
638	Materials 材料	TFDA-02033	ASTM	ASTM F3208 - 19	2019	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices	本標準已改版，請參考新版本標準。(ASTM F3208 - 20)
639	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	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)
640	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00129	ISO	ISO 4074:2002	2002	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)
641	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00452	ISO	ISO 8637:2004	2004	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)
642	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00453	ISO	ISO 8638:2004	2004	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)
643	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/	TFDA-00634	AAMI	AAMI RD5:2003	2007	Hemodialysis systems	本標準已廢除，請參考新標準。(IEC 60601-2-16:2012)

	婦產科學						
644	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00635	AAMI	AAMI RD16:2007	2007	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)
645	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00636	AAMI	AAMI RD17:2007	2007	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)
646	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	Reuse of hemodialyzers	本標準已改版，請參考新版本標準。(AAMI RD47:2008/(R)2013)
647	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00638	AAMI	AAMI RD52:2004	2004	Dialysate for hemodialysis	本標準已廢除，請參考新標準。(AAMI 23500:2014)
648	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00639	AAMI	AAMI RD61:2006	2007	Concentrates for hemodialysis	本標準已廢除，請參考新標準。(ISO 13958:2014)
649	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/	TFDA-00640	AAMI	AAMI RD62:2006	2007	Water treatment equipment for hemodialysis applications	本標準已廢除，請參考新標準。(ISO 26722:2014)

	婦產科學						
650	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	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)
651	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00911	ISO	ISO 8637:2010	2010	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)
652	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)
653	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00913	AAMI	RD5:2003/(R)2008	2008	Hemodialysis systems	本標準已廢除，請參考新標準。(IEC 60601-2-16:2012)
654	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)
655	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/	TFDA-00915	AAMI	RD52:2004/(R)2010 (incl A1 through A4)	2010	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)

	婦產科學						
656	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-00999	ISO	ISO 11663:2009	2009	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)
657	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-01000	ISO	ISO 13958:2009	2009	Concentrates for haemodialysis and related therapies	本標準已改版，請參考新版本標準。(ISO 13958:2014)
658	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-01001	ISO	ISO 13959:2009	2009	Water for haemodialysis and related therapies	本標準已改版，請參考新版本標準。(ISO 13959:2014)
659	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-01002	ISO	ISO 26722:1999	2009	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)
660	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	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)
661	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/	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)

	婦產科學						
662	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)
663	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-01248	ASTM	ASTM D1894-11	2011	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)
664	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-01249	ASTM	ASTM D412-06a(R2013)	2013	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)
665	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-01250	ASTM	ASTM F1828-97/(R)2013	2013	Standard Specification for Ureteral Stents	本標準已改版，請參考新版本標準。(ASTM F1828-17)
666	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	TFDA-01251	CEN	EN 1283:1996	1996	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)。
667	ObGyn/Gastroenterology 胃腸病科學及泌尿科學/	TFDA-01253	IEC	IEC 60601-2-16:2012	2012	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration	本標準已改版，請參考新版本標準。(IEC 60601-2-16:2018)

	婦產科學					equipment.	
668	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	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)
669	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	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)
670	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)
671	Ophthalmic 眼科學	TFDA-00130	ISO	ISO 10338:1996	1996	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)
672	Ophthalmic 眼科學	TFDA-00131	ISO	ISO 10339:1997	1997	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)
673	Ophthalmic 眼科學	TFDA-00132	ISO	ISO 10340:1995	1995	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)
674	Ophthalmic 眼科學	TFDA-00133	ISO	ISO 10344:1996	1996	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)
675	Ophthalmic 眼科學	TFDA-00134	ISO	ISO 11981:1999	2002	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 11981:2009)

676	Ophthalmic 眼科學	TFDA-00135	ISO	ISO 9913-1:1996	1996	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)
677	Ophthalmic 眼科學	TFDA-00136	ISO	ISO 9913-2:2000	2000	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)
678	Ophthalmic 眼科學	TFDA-00137	ISO	ISO 8321-1:2002	2002	Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 1: Rigid corneal and scleral contact lenses	本標準已廢除，請參考新標準。(ISO 18369-1:2006/amd 1:2009)
679	Ophthalmic 眼科學	TFDA-00138	ISO	ISO 8321-2:2000	2000	Ophthalmic optics -- Specifications for material, optical and dimensional properties of contact lenses -- Part 2: Single-vision hydrogel contact lenses	本標準已廢除，請參考新標準。(ISO 18369-2:2012)
680	Ophthalmic 眼科學	TFDA-00139	ISO	ISO 8599:1994	1994	Optics and optical instruments -- Contact lenses -- Determination of the spectral and luminous transmittance	本標準已廢除，請參考新標準。(ISO 18369-3:2006)
681	Ophthalmic 眼科學	TFDA-00140	ISO	ISO 9337-1:1999	1999	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)
682	Ophthalmic 眼科學	TFDA-00141	ISO	ISO 9338:1996	1996	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)
683	Ophthalmic 眼科學	TFDA-00142	ISO	ISO 9339-1:1996	1996	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)
684	Ophthalmic 眼科學	TFDA-00143	ISO	ISO 9339-2:1998	2000	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)
685	Ophthalmic 眼科	TFDA-00144	ISO	ISO 9340:1996	1996	Optics and optical instruments -- Contact lenses --	本標準已廢除，無取代標準。

	學					Determination of strains for rigid contact lenses	
686	Ophthalmic 眼科學	TFDA-00145	ISO	ISO 9341:1996	1996	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)
687	Ophthalmic 眼科學	TFDA-00146	ISO	ISO 9394:1998	1998	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)
688	Ophthalmic 眼科學	TFDA-00147	ISO	ISO 9914:1995	1995	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)
689	Ophthalmic 眼科學	TFDA-00148	ISO	ISO 11987:1997	1997	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)
690	Ophthalmic 眼科學	TFDA-00149	ISO	ISO 14534:2002	2002	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)
691	Ophthalmic 眼科學	TFDA-00150	ISO	ISO 14730:2000	2000	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)
692	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)
693	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)
694	Ophthalmic 眼科學	TFDA-00722	ISO	ISO 18369-3:2006	2006	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)
695	Ophthalmic 眼科學	TFDA-00723	ISO	ISO 18369-4:2006	2006	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)

696	Ophthalmic 眼科學	TFDA-00724	ISO	ISO 18369-1:2006/Amd 1:2009	2009	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)
697	Ophthalmic 眼科學	TFDA-00725	ISO	ISO 18369-2:2006	2006	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)
698	Ophthalmic 眼科學	TFDA-00934	ISO	ISO 11981:2009	2009	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)
699	Ophthalmic 眼科學	TFDA-00991	ISO	ISO 11986:1999	1999	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)
700	Ophthalmic 眼科學	TFDA-00992	ISO	ISO 8980-1:2004/Cor 1:2006	2006	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)
701	Ophthalmic 眼科學	TFDA-00993	ISO	ISO 8980-2:2004/Cor 1:2006	2006	Ophthalmic optics -- Uncut finished spectacle lenses -- Part 2: Specifications for progressive power lenses	本標準已改版，請參考新版本標準。(ISO 8980-1:2017)
702	Ophthalmic 眼科學	TFDA-00994	ISO	ISO 8980-3:2003	2003	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)
703	Ophthalmic 眼科學	TFDA-01326	ANSI	ANSI Z80.20-2010	2010	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)
704	Ophthalmic 眼科學	TFDA-01329	IEC	IEC 80601-2-58:2008	2008	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)
705	Ophthalmic 眼科	TFDA-01330	ISO	ISO 10936-1:2000	2000	Optics and optical instruments -- Operation microscopes --	本標準已改版，請參考新版

	學					Part 1: Requirements and test methods	本標準。(ISO 10936-1:2017)
706	Ophthalmic 眼科學	TFDA-01333	ISO	ISO 11979-10:2006	2006	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)
707	Ophthalmic 眼科學	TFDA-01334	ISO	ISO 11979-2:1999/Cor 1:2013	2003	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)
708	Ophthalmic 眼科學	TFDA-01336	ISO	ISO 11979-5:2006	2006	Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility	本標準已改版，請參考新版本標準。(ISO 11979-5:2020)
709	Ophthalmic 眼科學	TFDA-01337	ISO	ISO 11979-7:2014	2014	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)
710	Ophthalmic 眼科學	TFDA-01338	ISO	ISO 11979-8/Amd 1:2011	2011	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)
711	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)
712	Ophthalmic 眼科學	TFDA-01340	ISO	ISO 11986:2010	2010	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)
713	Ophthalmic 眼科學	TFDA-01343	ISO	ISO 18369-2:2012	2012	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)
714	Ophthalmic 眼科學	TFDA-01346	ANSI	ANSI Z80.7, 2013	2013	Ophthalmic Optics – Intraocular Lenses	本標準已改版，請參考新版本標準。(ANSI Z80.7-2013 (R2018))

715	Ophthalmic 眼科學	TFDA-01612	ANSI	ANSI Z80.36-2016	2016	Ophthalmic – Light Hazard Protection for Ophthalmic Instruments	本標準已改版，請參考新版本標準。(ANSI Z80.36-2021)
716	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)
717	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)
718	Orthopaedics 骨科學	TFDA-00080	ISO	ISO 14630:1997	1997	Non-active surgical implants -- General requirements	本標準已改版，請參考新版本標準。(ISO 14630:2012)
719	Orthopaedics 骨科學	TFDA-00081	ISO	ISO 5838-1:1995	1995	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)
720	Orthopaedics 骨科學	TFDA-00084	ISO	ISO 7207-1:1994	1994	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)
721	Orthopaedics 骨科學	TFDA-00085	ISO	ISO 7207-2:1998	1998	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)
722	Orthopaedics 骨科學	TFDA-00400	ISO	ISO 14243-1: 2002	2002	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)
723	Orthopaedics 骨	TFDA-00401	ISO	ISO 14243-2: 2000	2000	Implants for surgery -- Wear of total knee-joint prostheses --	本標準已改版，請參考新版

	科學					Part 2: Methods of measurement	本標準。(ISO 14243-2:2016)
724	Orthopaedics 骨科學	TFDA-00402	ISO	ISO 14243-3: 2004/Cor 1: 2006	2006	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)
725	Orthopaedics 骨科學	TFDA-00403	ISO	ISO 14602:1998	1998	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)
726	Orthopaedics 骨科學	TFDA-00404	ISO	ISO 21535:2002	2002	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)
727	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
728	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
729	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
730	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
731	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
732	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
733	Orthopaedics 骨	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	原採認標準已廢除

	科學					表面之螺絲	
734	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
735	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
736	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
737	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
738	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
739	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
740	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
741	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
742	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
743	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
744	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
745	Orthopaedics 骨	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

	科學						
746	Orthopaedics 骨科學	TFDA-00692	ISO	ISO 14630:2008	2008	Non-active surgical implants -- General requirements	本標準已改版，請參考新版本標準。(ISO 14630:2012)
747	Orthopaedics 骨科學	TFDA-00693	ISO	ISO 21535:2007	2007	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)
748	Orthopaedics 骨科學	TFDA-00885	ISO	ISO 14243-1:2009	2009	Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test — Amendment 1	本標準已改版，請參考新版本標準。(ISO 14243-1:2009/AMD 1:2020)
749	Orthopaedics 骨科學	TFDA-00886	ISO	ISO 14243-2:2009	2009	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)
750	Orthopaedics 骨科學	TFDA-01348	ASTM	ASTM D2990-09	2009	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)
751	Orthopaedics 骨科學	TFDA-01349	ASTM	ASTM D732-10	2010	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)
752	Orthopaedics 骨科學	TFDA-01350	ASTM	ASTM D790-10	2010	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)
753	Orthopaedics 骨科學	TFDA-01351	ASTM	ASTM E399-12	2012	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)
754	Orthopaedics 骨科學	TFDA-01352	ASTM	ASTM F1541-02/(R)2011	2011	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)

755	Orthopaedics 骨科學	TFDA-01353	ASTM	ASTM F2077-11	2011	Test Methods For Intervertebral Body Fusion Devices	本標準已改版，請參考新版本標準。(ASTM F2077-14)
756	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))
757	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))
758	Orthopaedics 骨科學	TFDA-01357	ASTM	ASTM F451-08	2008	Standard Specification for Acrylic Bone Cement	本標準已改版，請參考新版本標準。(ASTM F451-16)
759	Orthopaedics 骨科學	TFDA-01358	ASTM	ASTM F1717-11	2011	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)
760	Orthopaedics 骨科學	TFDA-01359	ASTM	ASTM F2193-02	2002	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)
761	Orthopaedics 骨科學	TFDA-01360	ISO	ISO 14242-1:2012	2012	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)
762	Orthopaedics 骨科學	TFDA-01361	ISO	ISO 14242-2:2000	2000	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)
763	Orthopaedics 骨科學	TFDA-01366	ISO	ISO 7207-2:2011	2011	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)
764	Orthopaedics 骨	TFDA-01367	ASTM	ASTM F1378–12	2012	Standard Specification for Shoulder Prostheses	本標準已改版，請參考新版

	科學						本標準。(ASTM F1378:2017)
765	Orthopaedics 骨科學	TFDA-01368	ASTM	ASTM F1714-96/(R)2013	2013	Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices.	本標準已改版，請參考新版本標準。(ASTM F1714-96/(R)2018)
766	Orthopaedics 骨科學	TFDA-01370	ASTM	ASTM F1829-98 (R2009).	2009	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)
767	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)
768	Orthopaedics 骨科學	TFDA-01372	ASTM	ASTM F2028-14	2014	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)
769	Orthopaedics 骨科學	TFDA-01373	ASTM	ASTM F2091-01 (R2012).	2012	Standard Specification for Acetabular Prostheses	本標準已改版，請參考新版本標準。(F2091-15)
770	Orthopaedics 骨科學	TFDA-01374	ASTM	ASTM F2180-02 (R 2011)	2011	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)
771	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)
772	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))
773	Orthopaedics 骨科學	TFDA-01377	ASTM	ASTM F2502-11	2011	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)

774	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))
775	Orthopaedics 骨科學	TFDA-01380	ASTM	ASTM F2665-09/(R)2014	2014	Standard Specification for Total Ankle Replacement Prosthesis	本標準已改版，請參考新版本標準。(ASTM F2665 - 21)
776	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))
777	Orthopaedics 骨科學	TFDA-01382	ASTM	ASTM F2996-13	2013	Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems	本標準已改版，請參考新版本標準。(ASTM F2996 - 20)
778	Orthopaedics 骨科學	TFDA-01389	ASTM	ASTM F2887-12	2012	Standard Specification For Total Elbow Prostheses	本標準已改版，請參考新版本標準。(ASTM F2887-17)
779	Orthopaedics 骨科學	TFDA-01619	ASTM	ASTM F116-12/(R)2016	2016	Standard Specification for Medical Screwdriver Bits	本標準已改版，請參考新版本標準。(ASTM F116 - 12(2021))
780	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))
781	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)
782	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)
783	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)

784	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)
785	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))
786	Orthopaedics 骨科學	TFDA-01630	ASTM	ASTM F2582-14	2014	Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components	本標準已改版，請參考新版本標準。(ASTM F2582 - 20)
787	Orthopaedics 骨科學	TFDA-01632	ASTM	ASTM F2979-14	2014	Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses	本標準已改版，請參考新版本標準。(ASTM F2979 - 20)
788	Orthopaedics 骨科學	TFDA-01634	ASTM	ASTM F451-16	2016	Standard Specification for Acrylic Bone Cement	本標準已改版，請參考新版本標準。(ASTM F451 - 21)
789	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)
790	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)
791	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)
792	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)

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793	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)
794	Orthopaedics 骨科學	TFDA-01910	ASTM	ASTM F2423 - 11(2016)	2016	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(2020))
795	Orthopaedics 骨科學	TFDA-01911	ASTM	ASTM F2624 - 12(2016)	2016	Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs	本標準已改版，請參考新版本標準。(ASTM F2624 - 12(2020))
796	Orthopaedics 骨科學	TFDA-02060	ASTM	ASTM E399 - 20	2020	Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Metallic Materials	本標準已改版，請參考新版本標準。(ASTM E399 - 20a)
797	Orthopaedics 骨科學	TFDA-02169	ASTM	F1264-16	2016	Standard Specification and Test Methods for Intramedullary Fixation Devices	本標準已改版，請參考新版本標準。(ASTM F1264 - 16e1)
798	Physical Medicine 物理醫學科學	TFDA-00151	ISO	ISO 7176-1:1999	1999	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)
799	Physical Medicine 物理醫學科學	TFDA-00152	ISO	ISO 7176-2:2001	2001	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)
800	Physical Medicine 物理醫學科學	TFDA-00153	ISO	ISO 7176-3:2003	2003	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)
801	Physical Medicine 物理醫學科學	TFDA-00154	ISO	ISO 7176-4:1997	1997	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)
802	Physical Medicine 物理醫學科學	TFDA-00155	ISO	ISO 7176-5:1986	1986	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)

803	Physical Medicine 物理醫學科學	TFDA-00156	ISO	ISO 7176-6:2001	2001	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)
804	Physical Medicine 物理醫學科學	TFDA-00158	ISO	ISO 7176-8:1998	1998	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)
805	Physical Medicine 物理醫學科學	TFDA-00159	ISO	ISO 7176-9:2001	2001	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)
806	Physical Medicine 物理醫學科學	TFDA-00160	ISO	ISO 7176-10:1988	1988	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)
807	Physical Medicine 物理醫學科學	TFDA-00161	ISO	ISO 7176-11:1992	1992	Wheelchairs - Part 11: Test Dummies	本標準已改版，請參考新版本標準。(ISO 7176-11:2012)
808	Physical Medicine 物理醫學科學	TFDA-00163	ISO	ISO 7176-14:1997	1997	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)
809	Physical Medicine 物理醫學科學	TFDA-00165	ISO	ISO 7176-16: 1997	1997	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)
810	Physical Medicine 物理醫學科學	TFDA-00166	ISO	ISO 7176-21:2003	2003	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)
811	Physical Medicine 物理醫學科學	TFDA-00167	ISO	ISO 7176-22:2000	2000	Wheelchairs -- Part 22: Set-up procedures	本標準已改版，請參考新版本標準。(ISO 7176-22:2014)
812	Physical Medicine 物理醫學科學	TFDA-00813	CNS	CNS 14964-3	2006	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))
813	Physical Medicine 物理醫學科學	TFDA-00818	CNS	CNS 14964-9	2007	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))
814	Physical Medicine 物理醫學科學	TFDA-00820	CNS	CNS 14964-11	2006	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))
815	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)
816	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)
817	Physical Medicine 物理醫學科學	TFDA-00997	CNS	CNS 15191	2010	木手杖	本標準已改版，請參考新版本標準。(CNS 15191 (2012))
818	Physical Medicine 物理醫學科學	TFDA-00998	CNS	CNS 15192	2010	可調式金屬手杖	本標準已改版，請參考新版本標準。(CNS 15192 (2013))
819	Physical Medicine 物理醫學科學	TFDA-01386	ISO	ISO 7176-16:2012	2012	Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method	本標準已改版，請參考新版本標準。(ISO 16840-10:2021)
820	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)
821	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)
822	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)
823	Physical Medicine	TFDA-02062	ISO	ISO 11199-2:2005	2005	Assistive products for walking manipulated by both arms —	本標準已改版，請參考新版

衛生福利部食品藥物管理署歷年廢除或改版之醫療器材標準清單

	物理醫學科學					Requirements and test methods — Part 2: Rollators	本標準。(ISO 11199-2:2021)
824	Software/Informatics 軟體/醫療資訊	TFDA-00090	IEC	ISO/IEC 12207:1995	2002	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)
825	Software/Informatics 軟體/醫療資訊	TFDA-00091	IEEE	IEEE 1012:1998	1998	Standard for Software Verification and Validation	本標準已改版，請參考新版本標準。(IEEE 1012:2012)
826	Software/Informatics 軟體/醫療資訊	TFDA-00092	IEEE	IEEE 1074:1997	1997	Standard for Developing Software Life Cycle Processes	本標準已改版，請參考新版本標準。(IEEE 1074-2006)
827	Software/Informatics 軟體/醫療資訊	TFDA-00344	CLSI	AUTO3-A	2000	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)
828	Software/Informatics 軟體/醫療資訊	TFDA-00345	CLSI	AUTO4-A	2001	Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard	本標準已廢除，無取代標準。
829	Software/Informatics 軟體/醫療資訊	TFDA-00438	IEC	IEC 62304:2006 - Ed. 1.0	2006	Medical device software - Software life cycle processes	本標準已改版，請參考新版本標準。(IEC 62304:2015)
830	Software/Informatics 軟體/醫療資訊	TFDA-00443	AAMI	AAMI TIR32:2004	2004	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)
831	Software/Informatics 軟體/醫療資	TFDA-00444	AAMI	ANSI/AAMI SW68:2001	2001	Medical device software—Software life cycle processes	本標準已廢除，請參考新標準。(IEC

	訊						62304:2006+A1:2015)
832	Software/Informatics 軟體/醫療資訊	TFDA-00479	IEC	CEI/IEC 61326-2-6:2005	2005	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)
833	Software/Informatics 軟體/醫療資訊	TFDA-00488	CLSI	AUTO1-A	2000	Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard	本標準已廢止
834	Software/Informatics 軟體/醫療資訊	TFDA-00490	CLSI	AUTO5-A	2001	Laboratory Automation: Electromechanical Interfaces; Approved Standard	本標準已廢除，無取代標準。
835	Software/Informatics 軟體/醫療資訊	TFDA-00491	CLSI	AUTO7-A	2004	Laboratory Automation: Data Content for Specimen Identification; Approved Standard	本標準已廢除，無取代標準。
836	Software/Informatics 軟體/醫療資訊	TFDA-00492	CLSI	AUTO8-P	2006	Protocols to Validate Laboratory Information Systems; Proposed Guideline	本標準已改版，請參考新版本標準。(AUTO8-A)
837	Software/Informatics 軟體/醫療資訊	TFDA-00493	CLSI	AUTO9-P	2006	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)
838	Software/Informatics 軟體/醫療資訊	TFDA-00578	IEC	ISO/IEC 25000-1:2007	2007	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)
839	Software/Informatics 軟體/醫療資	TFDA-00587	IEC	ISO/IEC 25051:2006	2006	Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Requirements for	本標準已改版，請參考新版本標準。(ISO/IEC

	訊					quality of Commercial Off-The-Shelf (COTS) software product and instructions for testing	25001:2014)
840	Software/Informatics 軟體/醫療資訊	TFDA-00645	CLSI	AUTO9-A	2006	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)
841	Software/Informatics 軟體/醫療資訊	TFDA-00736	CLSI	AUTO11-A	2006	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)
842	Software/Informatics 軟體/醫療資訊	TFDA-00900	ISO	ISO/IEC 12207:2008 ed2.0	2008	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)
843	Software/Informatics 軟體/醫療資訊	TFDA-00901	IEEE	IEEE 1012-2004	2005	IEEE Standard for Software Verification and Validation	本標準已改版，請參考新版本標準。(IEEE 1012:2012)
844	Software/Informatics 軟體/醫療資訊	TFDA-00902	IEEE	IEEE 1074-2006	2006	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)
845	Software/Informatics 軟體/醫療資訊	TFDA-00903	IEC	ANSI/AAMI/IEC 62304:2006	2006	Medical device software - Software life cycle processes	本標準已改版，請參考新版本標準。(IEC 62304:2015)
846	Software/Informatics 軟體/醫療資訊	TFDA-00960	CNS	CNS 14232	1998	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)
847	Software/Informat	TFDA-01052	AAMI	AAMI SW87:2012	2012	Application of quality management system concepts to	本標準已廢除，無取代標準。

	ics 軟體/醫療資訊					medical device data systems	
848	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)
849	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))
850	Software/Informatics 軟體/醫療資訊	TFDA-01068	IEEE	IEEE 1012:2012	2012	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)
851	Software/Informatics 軟體/醫療資訊	TFDA-01069	ISO	ISO/IEC 15026-4:2012	2012	Systems and software engineering — Systems and software assurance — Part 4: Assurance in the life cycle	本標準已改版，請參考新版本標準。(ISO/IEC/IEEE 15026-4:2021)
852	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)
853	Software/Informatics 軟體/醫療資訊	TFDA-01079	ISO	ISO/IEEE 11073-10417:2014	2012	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)
854	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)	本標準已改版，請參考新版本標準。(ISO/IEEE 11073-10418:2014/COR

						monitor	1:2016)
855	Software/Informatics 軟體/醫療資訊	TFDA-01084	ISO	ISO/IEEE 11073-20601:2010	2010	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)
856	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)
857	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)
858	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)
859	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)
860	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)
861	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)
862	Software/Informat	TFDA-02065	ISO	ISO/IEEE	2017	Health informatics — Device interoperability — Part 10101:	本標準已改版，請參考新版

	ics 軟體/醫療資訊			11073-10101+A11:2017		Point-of-care medical device communication — Nomenclature	本標準。(ISO/IEEE 11073-10101:2020)
863	Radiology 放射學科學	TFDA-00105	IEC	ISO 61217:2003	2002	Radiotherapy Equipment - Coordinates, movements, and scales	本標準已改版，請參考新版本標準。(IEC 61217:2011)
864	Radiology 放射學科學	TFDA-00106	IEC	IEC 60601-2-1:1998, A1:2002	1998	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)
865	Radiology 放射學科學	TFDA-00107	IEC	IEC 60601-2-8:1999	1999	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)
866	Radiology 放射學科學	TFDA-00108	IEC	IEC 60601-2-11:1997	1997	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)
867	Radiology 放射學科學	TFDA-00109	IEC	IEC 60601-2-28:1993	1993	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)
868	Radiology 放射學科學	TFDA-00110	IEC	IEC 60601-2-29:1999	1999	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)
869	Radiology 放射學科學	TFDA-00111	IEC	IEC 60601-2-32:1994	1994	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Associated Equipment of X-ray Equipment (1994)	本標準已廢除，請參考新標準。(IEC 60601-2-63 ed1.0:2012)
870	Radiology 放射學科學	TFDA-00112	IEC	IEC 60601-2-33:2002	2002	Medical Electrical Equipment - Part 2-33: Particular Requirements for the Safety of Magnetic Resonance	本標準已改版，請參考新版本標準。(IEC

						Equipment for Medical Diagnosis	60601-2-33:2015)
871	Radiology 放射學科學	TFDA-00113	IEC	IEC 60601-2-37:2001	2001	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)
872	Radiology 放射學科學	TFDA-00114	IEC	IEC 60601-2-43 :2000	2000	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)
873	Radiology 放射學科學	TFDA-00115	IEC	IEC 60601-2-44 :2002	2002	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)
874	Radiology 放射學科學	TFDA-00263	IEC	IEC 60601-2-7:2998	1998	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)
875	Radiology 放射學科學	TFDA-00264	IEC	IEC 60601-2-9:1996	1997	Medical electrical equipment - Part 2: Particular requirements for the safety of patient contact dosimeters used in radiotherapy with electrically connected radiation detectors - Ed. 2.0	本標準已廢除，請參考新標準。(IEC 60731:2011+A1:2016)
876	Radiology 放射學科學	TFDA-00267	ISO	ISO 2919:1999	1999	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)
877	Radiology 放射學科學	TFDA-00268	IEC	IEC 60731:1997	1997	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)
878	Radiology 放射學科學	TFDA-00272	IEC	IEC 60601-2-45:2001 Ed. 2.0	2001	Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray	本標準已改版，請參考新版本標準。(IEC

						equipment and mammographic stereotactic devices	60601-2-45:2015)
879	Radiology 放射學科學	TFDA-00273	IEC	IEC 60601-2-22:1995, Ed. 2.0	1996	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)
880	Radiology 放射學科學	TFDA-00274	ISO	ISO 11810-1:2005	2005	Optics and optical Instruments - Lasers and laser-related equipment - Test method for the laser-resistance of surgical drapes and/or patient-protective covers	本標準已被廢除，請參考新標準。(ISO 11810:2016)
881	Radiology 放射學科學	TFDA-00275	IEC	IEC 61674:1997	2002	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)
882	Radiology 放射學科學	TFDA-00276	ISO	ISO 11146:1999	2005	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)
883	Radiology 放射學科學	TFDA-00277	ISO	ISO 11254-1:2000	2000	Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 1: 1-on-1 test	本標準已廢除，請參考新標準。(ISO 21254-1:2011)
884	Radiology 放射學科學	TFDA-00278	ISO	ISO 11254-2:2001	2001	Lasers and laser-related equipment - Determination of laser-induced damage threshold of optical surfaces - Part 2: S-on-1 test	本標準已廢除，請參考新標準。(ISO 21254-1:2011)
885	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)
886	Radiology 放射學科學	TFDA-00280	ISO	ISO 11554:2003	2003	Optics and optical instruments - Lasers and laser-related equipment - Test methods for laser beam power, energy and	本標準已改版，請參考新版本標準。(ISO 11554:2006)

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887	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)
888	Radiology 放射學科學	TFDA-00284	CNS	CNS 14509-3	2001	Medical Electrical Equipment--Part 1-3: General Requirements for Safety-Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment (IDE IEC 60601-1-3)	本標準已被廢除，請參考新標準。(狀態: 廢止; 廢止日期: 105/10/19)
889	Radiology 放射學科學	TFDA-00413	IEC	IEC 61689:1996	1996	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)
890	Radiology 放射學科學	TFDA-00414	ISO	ISO 11146-2:2005	2005	Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 2: General astigmatic beams	本標準已改版，請參考新版本標準。(ISO 11146-2:2021)
891	Radiology 放射學科學	TFDA-00416	IEC	IEC 60601-2-5:2000	2000	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)
892	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)
893	Radiology 放射學科學	TFDA-00423	IEC	IEC 60825-1 - Consol. Ed. 1.2 (incl. am1+am2)	2001	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)
894	Radiology 放射學科學	TFDA-00424	IEC	IEC 60825-2 - Ed. 3.0	2004	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)

895	Radiology 放射學科學	TFDA-00425	IEC	IEC/TR 60825-3 - Ed. 1.0	1995	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)
896	Radiology 放射學科學	TFDA-00426	IEC	IEC 60825-4 - Consol. Ed. 1.2 (incl. am1+am2)	2003	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)
897	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
898	Radiology 放射學科學	TFDA-00428	IEC	IEC/TR 60825-8 - Ed. 1.0	1999	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)
899	Radiology 放射學科學	TFDA-00429	IEC	IEC/TR 60825-9 - Ed. 1.0	1999	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)
900	Radiology 放射學科學	TFDA-00430	IEC	IEC/TR 60825-10 - Ed. 1.0	2002	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)
901	Radiology 放射學科學	TFDA-00582	IEC	IEC 60601-2-45 :2001	2001	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)
902	Radiology 放射學科學	TFDA-00586	ISO	ISO 12052:2006	2006	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)
903	Radiology 放射學科學	TFDA-00697	IEC	IEC 60601-1-3 Edition 2.0 (2008-01)	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic	本標準已改版，請參考新版本標準。(IEC 60601-1-3:2013)

						X-ray equipment	
904	Radiology 放射學科學	TFDA-00698	IEC	IEC 60601-2-33 Consolidated Edition 2.2 (incl. am1+am2) (2008-04)	2008	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)
905	Radiology 放射學科學	TFDA-00699	IEC	IEC 60601-2-37:2007 Edition 2.0	2007	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)
906	Radiology 放射學科學	TFDA-00700	IEC	IEC 60825-1 Edition 2.0 (2007-03)	2007	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)
907	Radiology 放射學科學	TFDA-00701	IEC	IEC 61217 Consolidated Edition 1.2 (incl. am1+am2) (2008-04)	2008	Radiotherapy equipment - Coordinates, movements and scales	本標準已改版，請參考新版本標準。(IEC 61217:2011)
908	Radiology 放射學科學	TFDA-00702	IEC	IEC 61689 Edition 2.0 (2007-08)	2007	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)
909	Radiology 放射學科學	TFDA-00703	ISO	ISO 11554:2006	2006	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)
910	Radiology 放射學科學	TFDA-00728	IEC	IEC 60601-2-22 Edition 3.0 (2007-05)	2007	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser	本標準已改版，請參考新版本標準。(IEC 60601-2-22:2012)

						equipment	
911	Radiology 放射學科學	TFDA-00729	IEC	IEC 60601-2-11-am1 Edition 2.0 (2004-07)	2004	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)
912	Radiology 放射學科學	TFDA-00748	CNS	CNS 14176-1	2005	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)
913	Radiology 放射學科學	TFDA-00749	CNS	CNS 14176-2	2005	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)
914	Radiology 放射學科學	TFDA-00750	CNS	CNS 14176-3	1998	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)
915	Radiology 放射學科學	TFDA-00751	CNS	CNS 14176-4	1998	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)
916	Radiology 放射學科學	TFDA-00752	CNS	CNS 14176-5	1998	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)
917	Radiology 放射學科學	TFDA-00753	CNS	CNS 14176-6	2005	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)
918	Radiology 放射學科學	TFDA-00754	CNS	CNS 14176-7	1998	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)
919	Radiology 放射學科學	TFDA-00755	CNS	CNS 14176-8	2005	醫學數位影像及通信－第 8 部：訊息交換之網路通信支援	本標準已廢除，請參考新標準。(CNS 15211)
920	Radiology 放射學科學	TFDA-00756	CNS	CNS 14176-9	1998	醫學數位影像及通信－第 9 部：訊息交換之點對點通信支援	本標準已廢除，請參考新標準。(CNS 15211)
921	Radiology 放射學科學	TFDA-00757	CNS	CNS 14176-10	2007	醫學數位影像及通信－第 10 部：媒體交換之媒體儲存與檔案格式	本標準已廢除，請參考新標準。(CNS 15211)

922	Radiology 放射學科學	TFDA-00758	CNS	CNS 14176-11	2007	醫學數位影像及通信－第 11 部：媒體儲存應用規範	本標準已廢除，請參考新標準。(CNS 15211)
923	Radiology 放射學科學	TFDA-00759	CNS	CNS 14176-12	2007	醫學數位影像及通信－第 12 部：媒體交換之媒體格式與實體媒體	本標準已廢除，請參考新標準。(CNS 15211)
924	Radiology 放射學科學	TFDA-00760	CNS	CNS 14176-14	2007	醫學數位影像及通信－第 14 部：灰階標準顯示函數	本標準已廢除，請參考新標準。(CNS 15211)
925	Radiology 放射學科學	TFDA-00761	CNS	CNS 14176-15	2007	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)
926	Radiology 放射學科學	TFDA-00762	CNS	CNS 14176-18	2008	醫學數位影像及通信－第 18 部：DICOM 永續物件之資訊網存取	本標準已廢除，請參考新標準。(CNS 15211)
927	Radiology 放射學科學	TFDA-00763	NEMA	NEMA PS 3.1-2008	2008	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)
928	Radiology 放射學科學	TFDA-00764	NEMA	NEMA PS 3.2-2008	2008	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)
929	Radiology 放射學科學	TFDA-00765	NEMA	NEMA PS 3.3-2008	2008	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)
930	Radiology 放射學科學	TFDA-00766	NEMA	NEMA PS 3.4-2008	2008	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)
931	Radiology 放射學科學	TFDA-00767	NEMA	NEMA PS 3.5-2008	2008	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)
932	Radiology 放射學科學	TFDA-00768	NEMA	NEMA PS 3.6-2008	2008	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)
933	Radiology 放射學科學	TFDA-00769	NEMA	NEMA PS 3.7-2008	2008	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)

934	Radiology 放射學科學	TFDA-00770	NEMA	NEMA PS 3.8-2008	2008	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)
935	Radiology 放射學科學	TFDA-00771	NEMA	NEMA PS 3.10-2008	2008	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)
936	Radiology 放射學科學	TFDA-00772	NEMA	NEMA PS 3.11-2008	2008	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)
937	Radiology 放射學科學	TFDA-00773	NEMA	NEMA PS 3.12-2008	2008	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)
938	Radiology 放射學科學	TFDA-00774	NEMA	NEMA PS 3.14-2008	2008	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)
939	Radiology 放射學科學	TFDA-00775	NEMA	NEMA PS 3.15-2008	2008	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)
940	Radiology 放射學科學	TFDA-00776	NEMA	NEMA PS 3.16-2008	2008	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)
941	Radiology 放射學科學	TFDA-00777	NEMA	NEMA PS 3.17-2008	2008	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)

942	Radiology 放射學科學	TFDA-00778	NEMA	NEMA PS 3.18-2008	2008	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)
943	Radiology 放射學科學	TFDA-00891	IEC	IEC 60601-2-1 ed3.0 : 2009	2009	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)
944	Radiology 放射學科學	TFDA-00892	IEC	IEC 60601-2-28:2010 ed2.0	2010	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)
945	Radiology 放射學科學	TFDA-00893	IEC	IEC 60601-2-43:2010 ed2.0	2010	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)
946	Radiology 放射學科學	TFDA-00894	IEC	IEC 60601-2-44 ed3.0 : 2009	2009	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)
947	Radiology 放射學科學	TFDA-00895	IEC	IEC 60731-am1 ed2.0 : 2002	2002	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)
948	Radiology 放射學科學	TFDA-00897	IEC	IEC 60825-2 ed3.1 Consol. with am1	2007	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)
949	Radiology 放射學科學	TFDA-00899	IEC	IEC 60825-4 ed2.1 Consol. with am1 : 2009	2009	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)
950	Radiology 放射	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/	原採認標準已廢除

	學科學					或半導體偵檢器劑量計 (Medical electrical equipment – Dosimeter with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging (IDT: IEC 61674:1997))	
951	Radiology 放射學科學	TFDA-01394	IEC	IEC 60601-1-3:2013	2013	Amendment 2 - 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 60601-1-3:2008/AMD2:2021)
952	Radiology 放射學科學	TFDA-01396	IEC	IEC 60601-2-33:2013	2013	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)
953	Radiology 放射學科學	TFDA-01397	IEC	IEC 60601-2-44:2012	2012	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)
954	Radiology 放射學科學	TFDA-01398	IEC	IEC 60601-2-45:2011	2011	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)
955	Radiology 放射學科學	TFDA-01399	IEC	IEC 60601-2-54:2009+Corr1:2010	2009	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)

956	Radiology 放射學科學	TFDA-01401	IEC	IEC 60601-2-63 ed1.0	2012	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)
957	Radiology 放射學科學	TFDA-01402	IEC	IEC 60601-2-65:2012 ed1.0	2012	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)
958	Radiology 放射學科學	TFDA-01403	IEC	IEC 60601-2-8:2010 ed2.0	2010	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)
959	Radiology 放射學科學	TFDA-01405	IEC	IEC 60731:2011	2011	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)
960	Radiology 放射學科學	TFDA-01406	IEC	IEC 60825-1:2014	2014	Interpretation sheet 1 - 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/ISH1:2017)
961	Radiology 放射學科學	TFDA-01407	IEC	IEC 60825-2:2010	2010	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCSs)	本標準已改版，請參考新版本標準。(IEC 60825-2:2021)
962	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)
963	Radiology 放射	TFDA-01414	IEC	IEC 61223-3-5:2004	2004	Evaluation and routine testing in medical imaging	本標準已改版，請參考新版

	學科學					departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment - Edition 1.0	本標準。(IEC 61223-3-5:2004+CORR1:2006)
964	Radiology 放射學科學	TFDA-01422	IEC	IEC 62127-2:2007+A1:2013	2013	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)
965	Radiology 放射學科學	TFDA-01425	IEC	IEC/TS 62462:2007 ed1.0	2007	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)
966	Radiology 放射學科學	TFDA-01427	ISO	ISO 11146-1:2005	2005	Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams	本標準已改版，請參考新版本標準。(ISO 11146-1:2021)
967	Radiology 放射學科學	TFDA-01433	ISO	ISO/ASTM 51707:2005	2005	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)
968	Radiology 放射學科學	TFDA-01434	NEMA	NEMA PS 3.10-2011	2011	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)
969	Radiology 放射學科學	TFDA-01435	NEMA	NEMA PS 3.11-2011	2011	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)
970	Radiology 放射學科學	TFDA-01436	NEMA	NEMA PS 3.1-2011	2011	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)

971	Radiology 放射學科學	TFDA-01437	NEMA	NEMA PS 3.12-2011	2011	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)
972	Radiology 放射學科學	TFDA-01438	NEMA	NEMA PS 3.14-2011	2011	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)
973	Radiology 放射學科學	TFDA-01439	NEMA	NEMA PS 3.15-2011	2011	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)
974	Radiology 放射學科學	TFDA-01440	NEMA	NEMA PS 3.16-2011	2011	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)
975	Radiology 放射學科學	TFDA-01441	NEMA	NEMA PS 3.17-2011	2011	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)
976	Radiology 放射學科學	TFDA-01442	NEMA	NEMA PS 3.18-2011	2011	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)
977	Radiology 放射學科學	TFDA-01443	NEMA	NEMA PS 3.19-2011	2011	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)
978	Radiology 放射學科學	TFDA-01444	NEMA	NEMA PS 3.20-2011	2011	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)

979	Radiology 放射學科學	TFDA-01445	NEMA	NEMA PS 3.2-2011	2011	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)
980	Radiology 放射學科學	TFDA-01446	NEMA	NEMA PS 3.3-2011	2011	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)
981	Radiology 放射學科學	TFDA-01447	NEMA	NEMA PS 3.4-2011	2011	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)
982	Radiology 放射學科學	TFDA-01448	NEMA	NEMA PS 3.5-2011	2011	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)
983	Radiology 放射學科學	TFDA-01449	NEMA	NEMA PS 3.6-2011	2011	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 2016e)
984	Radiology 放射學科學	TFDA-01450	NEMA	NEMA PS 3.7-2011	2011	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)
985	Radiology 放射學科學	TFDA-01451	NEMA	NEMA PS 3.8-2011	2011	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)
986	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)
987	Radiology 放射	TFDA-01681	ASTM	ASTM F2978-13	2013	Standards Guide to Optimize Scan Sequences for Clinical	本標準已改版，請參考新版

	學科學					Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging	本標準。(ASTM F2978 - 20)
988	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
989	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)
990	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 Media Interchange	本標準已改版，請參考新版本標準。(DICOM PS3.10 2020c)
991	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)
992	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)
993	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)
994	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	本標準已改版，請參考新版本標準。(DICOM PS3.15

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995	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)
996	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)
997	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 (WADO)	本標準已改版，請參考新版本標準。(DICOM PS3.18 2020c)
998	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)
999	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)
1000	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)
1001	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)
1002	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

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1003	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)
1004	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)
1005	Radiology 放射學科學	TFDA-01699	NEMA	DICOM PS3.7 2016e	2016	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 2020c)
1006	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)
1007	Radiology 放射學科學	TFDA-01703	IEC	IEC 60601-2-1:2014	2014	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	本標準已改版，請參考新版本標準。(IEC 60601-2-1:2020)
1008	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)
1009	Radiology 放射學科學	TFDA-01706	IEC	IEC 60601-2-33:2010/AMD2:2015	2015	Corrigendum 2 - Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	本標準已改版，請參考新版本標準。(IEC 60601-2-33:2010/COR2:2016)
1010	Radiology 放射	TFDA-01717	IEC	IEC	2006	Evaluation and routine testing in medical imaging	原採認標準已廢除

	學科學			61223-3-5:2004+Corr 1:2006		departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment - Edition 1.0	
1011	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)
1012	Radiology 放射學科學	TFDA-02074	NEMA	DICOM PS3.1 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview	本標準已改版，請參考新版本標準。(DICOM PS3.1 2021c)
1013	Radiology 放射學科學	TFDA-02075	NEMA	DICOM PS3.10 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for Media Interchange	本標準已改版，請參考新版本標準。(DICOM PS3.10 2021c)
1014	Radiology 放射學科學	TFDA-02076	NEMA	DICOM PS3.11 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles	本標準已改版，請參考新版本標準。(DICOM PS3.11 2021c)
1015	Radiology 放射學科學	TFDA-02077	NEMA	DICOM PS3.12 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange	本標準已改版，請參考新版本標準。(DICOM PS3.12 2021c)
1016	Radiology 放射學科學	TFDA-02078	NEMA	DICOM PS3.14 2020bc	2020	Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function	本標準已改版，請參考新版本標準。(DICOM PS3.14 2021c)
1017	Radiology 放射學科學	TFDA-02079	NEMA	DICOM PS3.15 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 15: Security and System Management	本標準已改版，請參考新版本標準。(DICOM PS3.15

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1018	Radiology 放射學科學	TFDA-02080	NEMA	DICOM PS3.16 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource	本標準已改版，請參考新版本標準。(DICOM PS3.16 2021c)
1019	Radiology 放射學科學	TFDA-02081	NEMA	DICOM PS3.17 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 17: Explanatory Information	本標準已改版，請參考新版本標準。(DICOM PS3.17 2021c)
1020	Radiology 放射學科學	TFDA-02082	NEMA	DICOM PS3.18 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Access to DICOM Persistent Objects (WADO)	本標準已改版，請參考新版本標準。(DICOM PS3.18 2021c)
1021	Radiology 放射學科學	TFDA-02083	NEMA	DICOM PS3.19 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 19: Application Hosting	本標準已改版，請參考新版本標準。(DICOM PS3.19 2021c)
1022	Radiology 放射學科學	TFDA-02084	NEMA	DICOM PS3.2 2020c	2020	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 2021c)
1023	Radiology 放射學科學	TFDA-02085	NEMA	DICOM PS3.20 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 20: Transformation of DICOM to and from HL7 Standards	本標準已改版，請參考新版本標準。(DICOM PS3.20 2021c)
1024	Radiology 放射學科學	TFDA-02086	NEMA	DICOM PS3.3 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions	本標準已改版，請參考新版本標準。(DICOM PS3.3 2021c)
1025	Radiology 放射學科學	TFDA-02087	NEMA	DICOM PS3.4 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications	本標準已改版，請參考新版本標準。(DICOM PS3.4

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1026	Radiology 放射學科學	TFDA-02088	NEMA	DICOM PS3.5 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding	本標準已改版，請參考新版本標準。(DICOM PS3.5 2021c)
1027	Radiology 放射學科學	TFDA-02089	NEMA	DICOM PS3.6 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 6: Data Dictionary	本標準已改版，請參考新版本標準。(DICOM PS3.6 2021c)
1028	Radiology 放射學科學	TFDA-02090	NEMA	DICOM PS3.7 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 7: Message Exchange	本標準已改版，請參考新版本標準。(DICOM PS3.7 2021c)
1029	Radiology 放射學科學	TFDA-02091	NEMA	DICOM PS3.8 2020c	2020	Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange	本標準已改版，請參考新版本標準。(DICOM PS3.8 2021c)
1030	Sterility 滅菌	TFDA-00013	ISO	ISO 11134：1994	1994	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)
1031	Sterility 滅菌	TFDA-00014	ISO	ISO 11135：1994	1994	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)
1032	Sterility 滅菌	TFDA-00015	ISO	ISO 11137：1995, Amendment 1：2001	2001	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)
1033	Sterility 滅菌	TFDA-00025	ISO	ISO 11607:2000	2003	Packaging for terminally sterilized medical devices	本標準已廢除，請參考新標準。(ISO 11607-1:2009/Amd1:2014)

1034	Sterility 滅菌	TFDA-00026	ISO	ISO 11737-1:1995	1995	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)
1035	Sterility 滅菌	TFDA-00028	ISO	ISO 13408-1:1998	1998	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)
1036	Sterility 滅菌	TFDA-00029	ISO	ISO 13408-2:2003	2003	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)
1037	Sterility 滅菌	TFDA-00030	ISO	ISO 14160:1998	1998	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)
1038	Sterility 滅菌	TFDA-00031	ISO	ISO 14161:2000	2000	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)
1039	Sterility 滅菌	TFDA-00032	ISO	ISO 14644-1:1999	1999	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)
1040	Sterility 滅菌	TFDA-00033	ISO	ISO 14644-2:2000	2000	Cleanrooms and Associated Controlled Environments - Part 2: Specification for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1	本標準已改版，請參考新版本標準。(ISO 14644-2:2015)
1041	Sterility 滅菌	TFDA-00037	ISO	ISO 14937:2000	2003	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)
1042	Sterility 滅菌	TFDA-00225	AAMI	AAMI ST8:2001	1994	Hospital Steam Sterilizers	本標準已改版，請參考新版本標準。(AAMI ST8:2013)

1043	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)
1044	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)
1045	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)
1046	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)
1047	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)
1048	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)
1049	Sterility 滅菌	TFDA-00232	AAMI	AAMI ST50:2004	2004	Dry heat (heated air) sterilizers	本標準已改版，請參考新版本標準。(AAMI ST50:2004/(R)2010)
1050	Sterility 滅菌	TFDA-00233	CNS	CNS 14709	2013	Sterilization of medical devices - Validation and routine control of sterilisation by irradiation (MOD ISO 11737)	原採認標準已廢除
1051	Sterility 滅菌	TFDA-00349	ISO	ISO11607-1:2006	2006	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)
1052	Sterility 滅菌	TFDA-00350	ISO	ISO11607-2:2006	2006	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)
1053	Sterility 滅菌	TFDA-00353	ISO	ISO 14644-3:2005	2005	Cleanrooms and associated controlled environments —Part	本標準已改版，請參考新版

						3: Test methods	本標準。(ISO 14644-3:2019)
1054	Sterility 滅菌	TFDA-00356	ISO	ISO11137-1:2006	2006	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)
1055	Sterility 滅菌	TFDA-00357	ISO	ISO11137-2:2006	2006	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)
1056	Sterility 滅菌	TFDA-00358	ISO	ISO 11137-3:2006	2006	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)
1057	Sterility 滅菌	TFDA-00360	CEN	EN 556-1:2001	2001	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)
1058	Sterility 滅菌	TFDA-00513	ISO	ISO 11140-1:2005	2005	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)
1059	Sterility 滅菌	TFDA-00519	ISO	ISO 11138-1:2006	2006	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)
1060	Sterility 滅菌	TFDA-00520	ISO	ISO 11138-2:2006	2006	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)
1061	Sterility 滅菌	TFDA-00521	ISO	ISO 11138-3:2006	2006	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)
1062	Sterility 滅菌	TFDA-00522	ISO	ISO 11138-4:2006	2006	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)

1063	Sterility 滅菌	TFDA-00523	ISO	ISO 11138-5:2006	2006	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)
1064	Sterility 滅菌	TFDA-00527	ISO	ISO 11737-1:2006	2006	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)
1065	Sterility 滅菌	TFDA-00528	ISO	ISO 11737-2:1998	1998	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)
1066	Sterility 滅菌	TFDA-00531	ISO	ISO 13408-6:2005	2005	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)
1067	Sterility 滅菌	TFDA-00532	ISO	ISO 14644-8:2006	2006	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)
1068	Sterility 滅菌	TFDA-00534	AAMI	ST24:1999	2000	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)
1069	Sterility 滅菌	TFDA-00535	AAMI	ST55:2003	2004	Table-top steam sterilizers	本標準已改版，請參考新版本標準。(AAMI ST55:2010)
1070	Sterility 滅菌	TFDA-00536	AAMI	ST66:1999	1999	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)
1071	Sterility 滅菌	TFDA-00537	AAMI	ST77:2006	2007	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)
1072	Sterility 滅菌	TFDA-00538	ISO	ISO 15882:2003	2003	Sterilization of health care products -- Chemical indicators --	本標準已改版，請參考新版

						Guidance for selection, use and interpretation of results	本標準。(ISO 15882:2008)
1073	Sterility 滅菌	TFDA-00669	AAMI	ASTM ST24:1999/(R)2005	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)2009)
1074	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)
1075	Sterility 滅菌	TFDA-00671	AOAC	AOAC 6.2.03:2007	2007	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)
1076	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)
1077	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)
1078	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)
1079	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)
1080	Sterility 滅菌	TFDA-00678	ISO	ISO 11135-1:2007	2007	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	本標準已被廢除，請參考新標準。(ISO 11135:2014)
1081	Sterility 滅菌	TFDA-00679	ISO	ISO/TS 11135-2:2008	2008	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)
1082	Sterility 滅菌	TFDA-00863	ISO	ISO 13408-1:2008	2008	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)
1083	Sterility 滅菌	TFDA-00866	AAMI	ST8:2008	2009	Hospital steam sterilizers	本標準已改版，請參考新版

							本標準。(AAMI ST8:2013)
1084	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)
1085	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)
1086	Sterility 滅菌	TFDA-00869	AAMI	ST55:2003/(R)2008	2008	Table-top steam sterilizers	本標準已改版，請參考新版本標準。(AAMI ST55:2010)
1087	Sterility 滅菌	TFDA-01026	AAMI	AAMI ST55:2010	2010	Table-Top Steam Sterilizers	本標準已改版，請參考新版本標準。(AAMI ST55:2016)
1088	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))
1089	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)
1090	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)
1091	Sterility 滅菌	TFDA-01044	ISO	ISO 11137-1:2006/Amd 1:2013	2013	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)
1092	Sterility 滅菌	TFDA-01045	ISO	ISO 11137-2:2013	2013	Sterilization of health care products -- Radiation -- Part 2:	本標準已改版，請參考新版

						Establishing the sterilization dose	本標準。(ISO 11137-2 :2015)
1093	Sterility 滅菌	TFDA-01046	ISO	ISO 13408-1:2008/Amd 1:2013	2013	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)
1094	Sterility 滅菌	TFDA-01047	ISO	ISO 13408-6:2005/Amd 1:2013	2013	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 13408-6:2021)
1095	Sterility 滅菌	TFDA-01048	ISO	ISO 14160:2011	2011	Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	本標準已改版，請參考新版本標準。(ISO 14160:2020)
1096	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)
1097	Tissue Engineering 組織工程	TFDA-00737	ASTM	F2347-03	2003	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)
1098	Tissue Engineering 組織工程	TFDA-00738	ASTM	F2450-04	2004	Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products	本標準已改版，請參考新版本標準。(ASTM F2450-10)
1099	Tissue Engineering 組織	TFDA-00740	ASTM	F2315-03	2003	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)

	工程						
1100	Tissue Engineering 組織工程	TFDA-00742	ASTM	F2451-05	2005	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)
1101	Tissue Engineering 組織工程	TFDA-00948	ASTM	ASTM F2603-06	2007	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)
1102	Tissue Engineering 組織工程	TFDA-00739	ASTM	F2064-00(2006)	2006	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)
1103	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
1104	Tissue Engineering 組織工程	TFDA-01102	ASTM	ASTM F2347-11	2011	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)
1105	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
1106	Tissue Engineering 組織工程	TFDA-01105	ASTM	ASTM F2603-06/(R)2012	2012	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(2020))

1107	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)
1108	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)
1109	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)
1110	Tissue Engineering 組織工程	TFDA-01748	ISO	ISO 22442-2 :2015	2015	Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling	本標準已改版，請參考新版本標準。(ISO 22442-2:2020)
1111	Tissue Engineering 組織工程	TFDA-02105	ASTM	ASTM F2212 - 19	2019	Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)	本標準已改版，請參考新版本標準。(ASTM F2212 - 20)
1112	Neurology 神經學	TFDA-00116	IEC	IEC 60601-2-10 :1987	2001	Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators	本標準已改版，請參考新版本標準。(IEC 60601-2-10:2016)
1113	Neurology 神經學	TFDA-00606	ASTM	ASTM F647–94 (R2000)	1994	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)
1114	Neurology 神經學	TFDA-00608	ASTM	ASTM F1542-94 (R2000)	1994	Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips	本標準已廢除，無取代標準。

1115	Neurology 神經學	TFDA-00618	IEC	IEC 60601-2-23:1999	1999	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)
1116	Neurology 神經學	TFDA-00628	ISO	ISO 7197:1997	1997	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)
1117	Neurology 神經學	TFDA-00630	AAMI	AAMI NS28:1988/(R)2001	2001	Intracranial pressure monitoring devices	本標準已改版，請參考新版本標準。(AAMI NS28:1988/(R)2010)
1118	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))
1119	Neurology 神經學	TFDA-00933	AAMI	NS28:1988/(R)2006	2009	Intracranial pressure monitoring devices	本標準已改版，請參考新版本標準。(AAMI NS28:1988/(R)2010)
1120	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)
1121	Neurology 神經學	TFDA-01322	AAMI	ANSI/AAMI NS4:1985(R2009)	2009	Transcutaneous electrical nerve stimulators	本標準已改版，請參考新版本標準。(AAMI NS4:2013)
1122	Neurology 神經學	TFDA-01323	IEC	IEC 60601-2-10:2012 ed2.0	2012	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)

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1123	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)
1124	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要求(Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators)	原採認標準已廢除
1125	Neurology 神經學	TFDA-01927	AAMI	AAMI NS28:1988/(R)2015	2015	Intracranial Pressure Monitoring Devices	本標準已廢除，無取代標準。
1126	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	1995	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)
1127	General II (ES/EMC) 通用(醫療電子/電磁相容)	TFDA-00002	IEC	IEC 60601-1-1：2000	2000	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)
1128	General II (ES/EMC) 通用(醫療電子/電磁相容)	TFDA-00003	IEC	IEC 60601-1-2：2001	2001	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)
1129	General II (ES/EMC) 通用(醫療電子/電磁	TFDA-00004	IEC	IEC 60601-1-3：1994	1994	Medical Electrical Equipment - Part 1: General Requirements for Safety; General Requirements for 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)

	相容)						
1130	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-00005	IEC	IEC 60601-1-4：2000	2000	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)
1131	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-00086	IEC	IEC 60601-1-8:2003	2003	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)
1132	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	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)
1133	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-00434	IEC	IEC 60601-1:2005	2005	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)
1134	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	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)
1135	General II (ES/EMC) 通用	TFDA-00579	IEC	IEC 60601-1-2 ed3.0	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -	本標準已改版，請參考新版本標準。(IEC 60601-1-2:2014

	(醫療電子/電磁相容)					Collateral standard: Electromagnetic compatibility - Requirements and tests	ed4.0)
1136	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-00580	IEC	IEC 60601-1-6:2006	2006	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)
1137	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-00581	IEC	CEI/IEC 60601-2-22:1995	1995	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)
1138	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-00583	IEC	IEC 61326-1:2005	2005	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)
1139	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-00585	IEC	IEC/TR 62354:2005	2005	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)
1140	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	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)
1141	General II	TFDA-00889	IEC	IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General	本標準已改版，請參考新版

	(ES/EMC) 通用(醫療電子/電磁相容)			ed3.0 : 2010		requirements for basic safety and essential performance - Collateral standard: Usability	本標準。(IEC 60601-1-6:2013 ed3.1 Consol. with am1)
1142	General II (ES/EMC) 通用(醫療電子/電磁相容)	TFDA-00890	IEC	IEC/TR 62354:2009 ed2.0	2009	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)
1143	General II (ES/EMC) 通用(醫療電子/電磁相容)	TFDA-01005	IEC	IEC 60601-1:2005+Corr1:2012	2012	Interpretation Sheet 1 - Amendment 1 - 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/AMD1:2012/ISH1:2021)
1144	General II (ES/EMC) 通用(醫療電子/電磁相容)	TFDA-01006	IEC	IEC 60601-1-11:2010	2010	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	本標準已改版，請參考新版本標準。(IEC 60601-1-11:2015)
1145	General II (ES/EMC) 通用(醫療電子/電磁相容)	TFDA-01007	IEC	IEC 60601-1-2:2014 ed4.0	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	本標準已改版，請參考新版本標準。(IEC 60601-1-2:2014/AMD1:2020 CSV)
1146	General II (ES/EMC) 通用(醫療電子/電磁相容)	TFDA-01008	IEC	IEC 60601-1-6:2013	2013	Amendment 2 - 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 60601-1-6:2010/AMD2:2020)

1147	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-01009	IEC	IEC 60601-1-8:2012	2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	本標準已改版，請參考新版本標準。(IEC 60601-1-8:2006+AMD1:2012 +AMD2:2020 CSV)
1148	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
1149	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-01011	IEC	IEC 61326-1:2012	2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	本標準已改版，請參考新版本標準。(IEC 61326-1:2020)
1150	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-01016	ISO	ISO/TS 19218-1:2011	2011	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)
1151	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-01017	ISO	ISO/TS 19218-2:2012	2012	Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes - First Edition	本標準已廢除，無取代標準。
1152	General II (ES/EMC) 通用 (醫療電子/電磁	TFDA-01753	IEC	IEC 60601-1-10:2008+A1 :2015	2015	Amendment 2 - Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the	本標準已改版，請參考新版本標準。(IEC 60601-1-10:2007/AMD2:2020

	相容)					development of physiologic closed-loop controllers	)
1153	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-01754	IEC	IEC 60601-1-11:2015	2015	Amendment 1 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	本標準已改版，請參考新版本標準。(IEC 60601-1-11:2015/AMD1:2020)
1154	General II (ES/EMC) 通用 (醫療電子/電磁相容)	TFDA-01755	IEC	IEC 60601-1-12:2014	2014	Amendment 1 - Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	本標準已改版，請參考新版本標準。(IEC 60601-1-12:2014/AMD1:2020)