

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

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)

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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)

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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

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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 麻醉學	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

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	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)

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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/Am d1:2015	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

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						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

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							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

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	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)

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						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

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						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

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	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，請參考新標準

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	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

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	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))

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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

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	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

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	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

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	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 cardiectomy/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

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	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)

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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)

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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 Fissure 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)

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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)

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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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				10139-1:2005/Cor 1:2006		1:2006.	
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

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	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)

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

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/ 風險管理)	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)

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

	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/ 風險管理)	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)

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

	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/Cor1:201 1	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/ 風險管理)	TFDA-01508	IEC	IEC 62366-1:2015/COR1: 2016	2016	Medical devices –Part 1: Application of usability engineering to medical devices	本標準已改版，請參考新版 本標準。(IEC 62366-1:2015+AMD1:2020)

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

	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)

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

	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)

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

	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)

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

	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。

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	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)

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	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)

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	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)

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

	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)

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	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

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

	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)

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	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)

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

	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)

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

	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

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

	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—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—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—第七部份：鋁—塑膠組成之點滴瓶蓋	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)

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

	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)

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

	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)

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

	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/Am d.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)

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

	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)

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

	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)

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

	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)

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

	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)

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

	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)

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

	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)

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	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)

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

	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)

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

	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)

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

	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)

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

	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)

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	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))

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	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)

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	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)

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

	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)

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

	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)

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

	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)

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

	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)

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	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)

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	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)

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

	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)

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

	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+A MD1:2016	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+A MD1:2016	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)

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	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)

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	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)

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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)

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	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 NRSC 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)

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	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 Immunofluorescence 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)

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	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)

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	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)

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	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)

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	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)

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	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)

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	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

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	Diagnosics 體外 診斷醫療器材					characterization	本標準。(MM10-A)
505	In Vitro Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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

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	Diagnosics 體外 診斷醫療器材					Molecular Methods; Approved Guideline	本標準。(MM14-A2)
513	In Vitro Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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))

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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

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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)

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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

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	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)

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	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	Immunoglobulin 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

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	Diagnosics 體外 診斷醫療器材					Guideline	本標準。(C49)
560	In Vitro Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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

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	Diagnosics 體外 診斷醫療器材					Approved Guideline—Third Edition	
568	In Vitro Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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 Diagnosics 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)

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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)

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	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)

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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

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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	AATC C	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	AATC C	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	AATC C	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

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						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 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 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 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 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 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 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 本標準。(ASTM F899 - 20)
619	Materials 材料	TFDA-01580	AATC C	AATCC 128-2013	2013	Water Resistance: Hydrostatic Pressure Test	本標準已改版，請參考新 本標準。(AATCC 128:2017)

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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 -

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						(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)

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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)

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	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)

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	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)

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	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)

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	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)

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	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)

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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。

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	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	Ophthalmic 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)

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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 Physicochemical 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

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	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 11979-9:2018)
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))

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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 科學	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

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	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

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	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 骨科學	TFDA-00568	CNS	CNS 13382-30	1996	外科植入物-成人之股骨端固定用裝置	原採認標準已廢除

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	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 K _{Ic} 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)

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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 骨科學	TFDA-01367	ASTM	ASTM F1378-12	2012	Standard Specification for Shoulder Prostheses	本標準已改版，請參考新版

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	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)

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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)

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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 K _{Ic} 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)

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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

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							(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

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	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/醫療資訊	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

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	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/醫療資訊	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

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	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/Informatics 軟體/醫療資訊	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。

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	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)

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						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/Informatics 軟體/醫療資訊	TFDA-02065	ISO	ISO/IEEE	2017	Health informatics — Device interoperability — Part 10101:	本標準已改版，請參考新版

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	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

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						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

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						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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						temporal characteristics	
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)

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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)

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						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)

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

						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，請參考新舊本標準。(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)

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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)

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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)

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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 放射學科學	TFDA-01391	CNS	CNS 15585	2013	醫電設備電性安全—X 射線診斷造影使用之游離腔及/	原採認標準已廢除

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	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)

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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 放射學科學	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

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	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)

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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)

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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

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	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，請參考新舊本標準。(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，請參考新舊本標準。(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，請參考新舊本標準。(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，請參考新舊本標準。(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，請參考新舊本標準。(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，請參考新舊本標準。(DICOM PS3.15

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						Profiles	2020c)
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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							2020c)
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/AM D2:2015	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 放射學科學	TFDA-01717	IEC	IEC	2006	Evaluation and routine testing in medical imaging	原採認標準已廢除

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	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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						Profiles	2021c)
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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							2021c)
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)

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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 Controlled 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)

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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

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						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)

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

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

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						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

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							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

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						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)

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	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))

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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。

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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)

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	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. aml)	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

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	(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

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	(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/IS H1:2021)
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)

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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 相容)	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)

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	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)