

115 年度衛生福利部食品藥物管理署採認醫療器材標準

附件 1、115 年度醫療器材標準採認清單(共 1,393 項)

編號	標準類別	標準組織 名稱	標準號碼	版本/ 年份	標準名稱	備註說明
1.	1 Anesthesias 麻醉學	ISO	ISO 13320	2020	Particle size analysis — Laser diffraction methods	原採認標準
2.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-84	2023	Medical electrical equipment Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment	原採認標準版本更新
3.	1 Anesthesias 麻醉學	ISO	ISO 10651-4	2023	Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators	原採認標準
4.	1 Anesthesias 麻醉學	ISO	ISO 10651-5	2006	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas powered emergency resuscitators	原採認標準
5.	1 Anesthesias 麻醉學	CNS	CNS 14961	2005	小型醫療氣體鋼瓶－銷針標示軛式閥接頭	原採認標準
6.	1 Anesthesias 麻醉學	CNS	CNS 14962	2005	氣體鋼瓶－工業與醫療氣體鋼瓶之閥保護帽與閥保護套－設計、結構與試驗	原採認標準
7.	1 Anesthesias 麻醉學	CNS	CNS 14963	2005	醫療用氣體混合器－獨立式氣體混合器	原採認標準
8.	1 Anesthesias 麻醉學	CNS	CNS 15004	2006	醫療氣體管線系統使用之氧氣濃縮機	原採認標準
9.	1 Anesthesias 麻醉學	CNS	CNS 15006	2006	連接於醫療氣體管線系統終端單元之流量計裝置	原採認標準
10.	1 Anesthesias 麻醉學	ISO	ISO 5362	2024	Anaesthetic and respiratory equipment - Anaesthetic reservoir bags	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

11.	1 Anesthesias 麻醉學	CNS	CNS 14776	2022	醫用面罩對合成血液穿透阻力的試驗法—以已知速度定量的水平噴灑 (Method of test for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity))	原採認標準
12.	1 Anesthesias 麻醉學	CNS	CNS 14777	2003	醫用面罩空氣交換壓力之試驗法 (Method of test for air exchange pressure of medical face mask)	原採認標準
13.	1 Anesthesias 麻醉學	CNS	CNS 6636	2013	呼吸防護裝置-氣體濾材及組合型濾材-要求、試驗、標示 (Respiratory protective devices - Gas filters and combined filters - Requirements, testing, marking)	原採認標準
14.	1 Anesthesias 麻醉學	ISO	ISO 23328-1	2003	Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance	原採認標準
15.	1 Anesthesias 麻醉學	ISO	ISO 23328-2	2002	Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects	原採認標準
16.	1 Anesthesias 麻醉學	ISO	ISO 26782	2009	Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans	原採認標準
17.	1 Anesthesias 麻醉學	ASTM	ASTM G175	2024	Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications	原採認標準
18.	1 Anesthesias 麻醉學	ISO	ISO 10079-2	2022	Medical suction equipment - Part 2: Manually powered suction equipment	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

19.	1 Anesthesias 麻醉學	ISO	ISO 10079-3	2022	Medical suction equipment Part 3: Suction equipment powered from a vacuum or pressure source	原採認標準
20.	1 Anesthesias 麻醉學	ISO	ISO 14408	2016	Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information	原採認標準
21.	1 Anesthesias 麻醉學	ISO	ISO 23747	2015	Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans	原採認標準
22.	1 Anesthesias 麻醉學	ISO	ISO 5360	2016	Anaesthetic vaporizers - Agent-specific filling systems	原採認標準
23.	1 Anesthesias 麻醉學	ISO	ISO 5361	2023	Anaesthetic and respiratory equipment — Tracheal tubes and connectors	原採認標準
24.	1 Anesthesias 麻醉學	ISO	ISO 5364	2016	Anaesthetic and respiratory equipment - Oropharyngeal airways	原採認標準
25.	1 Anesthesias 麻醉學	ISO	ISO 5366	2016	Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors	原採認標準
26.	1 Anesthesias 麻醉學	ISO	ISO 5367	2023	Anaesthetic and respiratory equipment — Breathing sets and connectors	原採認標準
27.	1 Anesthesias 麻醉學	ISO	ISO 7376	2025	Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation Amendment 1: Clarification of optical output and illumination requirements	原採認標準版本更新
28.	1 Anesthesias 麻醉學	ISO	ISO 80369-7	2021	Small-bore connectors for liquids and gases in	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	
29.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-67	2020	Medical electrical equipment — Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment	原採認標準
30.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-69	2020	Medical electrical equipment — Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment	原採認標準
31.	1 Anesthesias 麻醉學	ISO	ISO 10524-1	2023	Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices	原採認標準
32.	1 Anesthesias 麻醉學	ISO	ISO 10524-2	2018	Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators	原採認標準
33.	1 Anesthesias 麻醉學	ISO	ISO 17510	2015	Medical devices - Sleep apnoea breathing therapy - Masks and application accessories	原採認標準
34.	1 Anesthesias 麻醉學	ISO	ISO 5356-1	2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets	原採認標準
35.	1 Anesthesias 麻醉學	ISO	ISO 5359	2017	Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases	原採認標準
36.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-55	2023	Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Amendment 1	
37.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-70	2020	Medical electrical equipment — Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment	原採認標準
38.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-74	2021	Medical electrical equipment—Part 2 – 74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment	原採認標準
39.	1 Anesthesias 麻醉學	ISO	ISO 10079-1	2022	Medical suction equipment — Part 1: Electrically powered suction equipment	原採認標準
40.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-13	2022	Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	原採認標準
41.	1 Anesthesias 麻醉學	EN	EN ISO 27427	2023	Anaesthetic and respiratory equipment - Nebulizing systems and components	原採認標準
42.	1 Anesthesias 麻醉學	ISO	ISO 10524-3	2019	Pressure regulators for use with medical gasesPart 3: Pressure regulators integrated with cylinder valves (VIPRs)	原採認標準
43.	1 Anesthesias 麻醉學	ISO	ISO 80369-1	2018	Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements	原採認標準
44.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-12	2023	Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

45.	1 Anesthesias 麻醉學	ISO	ISO 8836	2019	Suction catheters for use in the respiratory tract	原採認標準
46.	1 Anesthesias 麻醉學	ISO	ISO 5356-2	2019	Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors	原採認標準
47.	1 Anesthesias 麻醉學	NFPA	NFPA 99	2024	Health Care Facilities Code	原採認標準
48.	1 Anesthesias 麻醉學	ISO	ISO 16628	2022	Anaesthetic and respiratory equipment - Tracheobronchial tubes	原採認標準
49.	1 Anesthesias 麻醉學	ISO	ISO 10079-4	2021	Medical suction equipment - Part 4: General requirements	原採認標準
50.	1 Anesthesias 麻醉學	ISO	ISO 26825	2020	Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours design and performance	原採認標準
51.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-87	2021	Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators	原採認標準
52.	1 Anesthesias 麻醉學	ASME	ASME PVHO-1	2023	Safety Standard for Pressure Vessels for Human Occupancy	原採認標準版本更新
53.	1 Anesthesias 麻醉學	ISO	ISO 18778	2022	Respiratory equipment - Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors	原採認標準
54.	1 Anesthesias 麻醉學	CGA	CGA V-5	2019	Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

55.	1 Anesthesias 麻醉學	CGA	CGA V-7.1	2021	Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases	原採認標準
56.	1 Anesthesias 麻醉學	CGA	CGA V-1	2023	Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connection	原採認標準版本更新
57.	1 Anesthesias 麻醉學	CGA	CGA C-9	2019	Standard Color Marking of Compressed Gas Containers for Medical Use	原採認標準
58.	1 Anesthesias 麻醉學	ISO	ISO 11712	2023	Anaesthetic and respiratory equipment - Supralaryngeal airways and connectors	原採認標準
59.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-72	2023	Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients	原採認標準
60.	1 Anesthesias 麻醉學	ISO	ISO 11195	2018	Gas mixers for medical use - Stand-alone gas mixers	原採認標準
61.	1 Anesthesias 麻醉學	ISO	ISO 18190	2025	Anaesthetic and respiratory equipment - General requirements for airways and related equipment	115 年度新增採認標準
62.	1 Anesthesias 麻醉學	ISO	ISO 80369-2	2024	Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications	115 年度新增採認標準
63.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-90	2021	Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment	115 年度新增採認標準
64.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-79	2024	Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential	115 年度新增採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					performance of ventilatory support equipment for ventilatory impairment	
65.	1 Anesthesias 麻醉學	ISO	ISO 80601-2-80	2024	Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency	115 年度新增採認標準
66.	1 Anesthesias 麻醉學	ISO	ISO 4135	2022	Anaesthetic and respiratory equipment - Vocabulary	115 年度新增採認標準
67.	1 Anesthesias 麻醉學	ISO	ISO 9360-1	2000	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml	115 年度新增採認標準
68.	1 Anesthesias 麻醉學	ISO	ISO 9360-2	2001	Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml	115 年度新增採認標準
69.	1 Anesthesias 麻醉學	ISO	ISO 23371	2022	Anaesthetic and respiratory equipment - Cuff pressure indication control and regulation devices	115 年度新增採認標準
70.	2 Biocompatibility 生物相容性	ISO	ISO 10993-14	2001	Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics	原採認標準
71.	2 Biocompatibility 生物相容性	ISO	ISO 10993-17	2023	Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					device constituents	
72.	2 Biocompatibility 生物相容性	CNS	CNS 14393-7	2005	醫療器材生物性評估－第 7 部：環氧乙烷滅菌之殘留物 Biological evaluation of medical devices - Part 7: ethylene oxide sterilisation residuals	原採認標準
73.	2 Biocompatibility 生物相容性	CNS	CNS 14393-8	2005	醫療器材生物性評估－第 8 部：生物測試用參考材料之選擇及資格認定 Biological evaluation of medical devices - Part 8: Selection and qualification of reference materials for biological tests (ISO 10993-8:2000)	原採認標準
74.	2 Biocompatibility 生物相容性	CNS	CNS 14393-10	2005	醫療器材生物性評估－第 10 部：刺激性及延遲型過敏性測試 Biological evaluation of medical devices - Part 10 : tests for irritation and sensitisation	原採認標準
75.	2 Biocompatibility 生物相容性	CNS	CNS 14393-12	2005	醫療器材生物性評估－第 12 部：樣品製備及參考材料 Biological evaluation of medical devices - Part 12 : sample preparation and reference materials	原採認標準
76.	2 Biocompatibility 生物相容性	CNS	CNS 14393-6	2004	醫療器材生物性評估－第六部分：植入後的局部效應測試 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	原採認標準
77.	2 Biocompatibility 生物相容性	CNS	CNS 14393-11	2005	醫療器材生物性評估－第 11 部：全身毒性測試 Biological evaluation of medical devices - Part 11: tests for systemic toxicity	原採認標準
78.	2 Biocompatibility 生物相容性	ISO	ISO/TS 10993-20	2006	Biological evaluation of medical devices —Part 20: Principles and methods for immunotoxicology testing of medical devices	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

79.	2 Biocompatibility 生物相容性	ISO	ISO 10993-2	2022	Biological evaluation of medical devices -- Part 2: Animal welfare requirements	原採認標準
80.	2 Biocompatibility 生物相容性	CNS	CNS14393-1	2004	醫療器材生物性評估-第一部份：評估與試驗	原採認標準
81.	2 Biocompatibility 生物相容性	CNS	CNS14393-2	2004	醫療器材生物性評估-第二部份：動物福利之規定	原採認標準
82.	2 Biocompatibility 生物相容性	CNS	CNS14393-3	2004	醫療器材生物性評估-第三部份：基因毒性、致癌性與生殖毒性之試驗	原採認標準
83.	2 Biocompatibility 生物相容性	CNS	CNS14393-4	2004	醫療器材生物性評估-第四部份：血液接觸特性測試方法的選擇	原採認標準
84.	2 Biocompatibility 生物相容性	CNS	CNS14393-5	2004	醫療器材生物性評估-第五部份：體外細胞毒性試驗	原採認標準
85.	2 Biocompatibility 生物相容性	CNS	CNS14393-9	2005	醫療器材生物性評估-第九部份：潛在降解產物之鑑別與定量 分析架構	原採認標準
86.	2 Biocompatibility 生物相容性	CNS	CNS14393-13	2005	醫療器材生物性評估-第十三部份：聚合物醫療器材降解產物 之鑑別與定量	原採認標準
87.	2 Biocompatibility 生物相容性	CNS	CNS14393-14	2005	醫療器材生物性評估-第十四部份：陶瓷降解產物之鑑別與定 量	原採認標準
88.	2 Biocompatibility 生物相容性	CNS	CNS14393-15	2006	醫療器材生物性評估-第十五部份：金屬集合金之降解產物的 鑑別與定量	原採認標準
89.	2 Biocompatibility 生物相容性	CNS	CNS14393-16	2006	醫療器材生物性評估-第十六部份：降解及可溶出物之毒性動 力學之研究設計	原採認標準
90.	2 Biocompatibility 生物相容性	CNS	CNS 15153	2007	醫療器材生物性評估—第 17 部：可溶出物質容忍 限量之建立	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

91.	2 Biocompatibility 生物相容性	CNS	CNS 15154	2007	醫療器材生物性評估－第 18 部：材料之化學特性	原採認標準
92.	2 Biocompatibility 生物相容性	CNS	CNS 15155	2007	醫療器材生物性評估－第 19 部：材料之物理化學、形態及拓撲學的特性分析	原採認標準
93.	2 Biocompatibility 生物相容性	CNS	CNS 14393-20	2009	醫療器材生物性評估－第 20 部：醫療器材免疫毒理學試驗之原理與方法	原採認標準
94.	2 Biocompatibility 生物相容性	ISO	ISO 10993-5	2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	原採認標準
95.	2 Biocompatibility 生物相容性	ISO	ISO 10993-13	2010	Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices	原採認標準
96.	2 Biocompatibility 生物相容性	ISO	ISO 10993-10	2021	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	原採認標準
97.	2 Biocompatibility 生物相容性	ASTM	ASTM F750	2020	Standard Practice for Evaluating Acute Systemic Toxicity of Material Extracts by Systemic Injection in the Mouse	原採認標準
98.	2 Biocompatibility 生物相容性	ASTM	ASTM F813	2020	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	原採認標準
99.	2 Biocompatibility 生物相容性	ISO	ISO 10993-12	2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials	原採認標準
100.	2 Biocompatibility 生物相容性	ISO	ISO 10993-3	2014	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	原採認標準
101.	2 Biocompatibility 生物相容性	ISO	ISO 10993-6	2016	Biological evaluation of medical devices, Part 6:	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物相容性				Tests for local effects after implantation	
102.	2 Biocompatibility 生物相容性	ISO	AAMI/ISO TIR37137	2014	Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants	原採認標準
103.	2 Biocompatibility 生物相容性	ISO	ISO/TR 10993-33	2015	Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3	原採認標準
104.	2 Biocompatibility 生物相容性	ASTM	ASTM F720	2024	Standard Test Method for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test	原採認標準版本更新
105.	2 Biocompatibility 生物相容性	ISO	ISO 10993-11	2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	原採認標準
106.	2 Biocompatibility 生物相容性	ISO	ISO 10993-16	2017	Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables	原採認標準
107.	2 Biocompatibility 生物相容性	ISO	ISO 10993-4	2025	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood Amendment 1	原採認標準版本更新
108.	2 Biocompatibility 生物相容性	ISO	ISO 18562-2	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter	原採認標準
109.	2 Biocompatibility 生物相容性	ISO	ISO 18562-4	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate	原採認標準
110.	2 Biocompatibility 生物相容性	ASTM	ASTM F2382	2024	Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Partial Thromboplastin Time (PTT)	
111.	2 Biocompatibility 生物相容性	ISO	ISO 10993-1	2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	原採認標準
112.	2 Biocompatibility 生物相容性	ISO	ISO 18562-1	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process	原採認標準
113.	2 Biocompatibility 生物相容性	ISO	ISO 18562-3	2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 3: Tests for emissions of volatile organic substances	原採認標準
114.	2 Biocompatibility 生物相容性	ASTM	ASTM F2148	2018	Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	原採認標準
115.	2 Biocompatibility 生物相容性	ISO	ISO 10993-15	2019	Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloy	原採認標準
116.	2 Biocompatibility 生物相容性	ISO	ISO 10993-18	2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process Amendment 1: Determination of the uncertainty factor	原採認標準
117.	2 Biocompatibility 生物相容性	ISO	ISO/TS 10993-19	2020	Biological evaluation of medical devices —Part 19: Physico-chemical, morphological and topographical	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					characterization of materials	
118.	2 Biocompatibility 生物相容性	ISO	ISO 10993-9	2019	Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products	原採認標準
119.	2 Biocompatibility 生物相容性	ASTM	ASTM F719	2020	Standard Practice for Testing Materials in Rabbits for Primary Skin Irritation	原採認標準
120.	2 Biocompatibility 生物相容性	ASTM	ASTM F749	2020	Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	原採認標準
121.	2 Biocompatibility 生物相容性	ISO	ISO 10993-7	2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals Amendment 1: Applicability of allowable limits for neonates and infants	原採認標準
122.	2 Biocompatibility 生物相容性	ASTM	ASTM F619	2020	Standard Practice for Extraction of Materials Used in Medical Devices	原採認標準
123.	2 Biocompatibility 生物相容性	ASTM	ASTM F1408	2020	Standard Practice for Subcutaneous Screening Test for Implant Materials	原採認標準
124.	2 Biocompatibility 生物相容性	CEN ISO	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation	原採認標準
125.	2 Biocompatibility 生物相容性	CEN	EN ISO 10993-10	2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	原採認標準
126.	2 Biocompatibility 生物相容性	ASTM	ASTM F1983	2023	Standard Practice for Assessment of Selected Tissue Effects of Absorbable Biomaterials for Implant Applications	原採認標準
127.	2 Biocompatibility 生物相容性	ASTM	ASTM F1904	2023	Standard Guide for Testing the Biological Responses	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物相容性				to Medical Device Particulate Debris and Degradation Products in vivo	
128.	2 Biocompatibility 生物相容性	ASTM	ASTM F763	2022	Standard Practice for Short-Term Intramuscular Screening of Implantable Medical Device Materials	原採認標準
129.	2 Biocompatibility 生物相容性	ASTM	ASTM F981	2023	Standard Practice for Assessment of Muscle and Bone Tissue Responses to Long-Term Implantable Materials Used in Medical Devices	原採認標準
130.	2 Biocompatibility 生物相容性	ASTM	ASTM E1262	2024	Standard Guide for Performance of Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay	115 年度新增採認標準
131.	2 Biocompatibility 生物相容性	ASTM	ASTM F1439	2024	Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	115 年度新增採認標準
132.	2 Biocompatibility 生物相容性	ASTM	ASTM F1877	2024	Standard Practice for Characterization of Particles	115 年度新增採認標準
133.	2 Biocompatibility 生物相容性	ASTM	ASTM F756	2017	Standard Practice for Assessment of Hemolytic Properties of Materials	115 年度新增採認標準
134.	2 Biocompatibility 生物相容性	ISO	ISO/TS 21726	2019	Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents	115 年度新增採認標準
135.	3 Cardiovascular 心臟血管醫學	ASTM	ASTM F746	2021	Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	原採認標準
136.	3 Cardiovascular 心臟血管醫學	ISO	ISO 8637-3	2024	Extracorporeal systems for blood purification - Part 3: Plasmafilters	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

137.	3 Cardiovascular 血管醫學	心臟	ISO	ISO 81060-2	2024	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	原採認標準
138.	3 Cardiovascular 血管醫學	心臟	ASTM	ASTM F3320	2018	Standard Guide for Coating Characterization of Drug-Coated Balloons	原採認標準
139.	3 Cardiovascular 血管醫學	心臟	ISO	ISO 11318	2002	Cardiac Defibrillators - Connector Assembly for Implantable Defibrillators - Dimensional and Test Requirements	原採認標準
140.	3 Cardiovascular 血管醫學	心臟	CNS	CNS 13075	2007	非侵入式自動血壓計	原採認標準
141.	3 Cardiovascular 血管醫學	心臟	CNS	CNS 15041-1	2007	非侵入式血壓計－第 1 部：一般規定	原採認標準
142.	3 Cardiovascular 血管醫學	心臟	CNS	CNS 15041-2	2007	非侵入式血壓計－第 2 部：機械式血壓計之補充規定	原採認標準
143.	3 Cardiovascular 血管醫學	心臟	CNS	CNS 15041-3	2007	非侵入式血壓計－第 3 部：機電式血壓量測系統的補充規定	原採認標準
144.	3 Cardiovascular 血管醫學	心臟	OIML	OIML R16-2	2005	Non-invasive automated sphygmomanometers	原採認標準
145.	3 Cardiovascular 血管醫學	心臟	CEN	EN 1060-4	2004	Non-invasive sphygmomanometers—Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	原採認標準
146.	3 Cardiovascular 血管醫學	心臟	AAMI	AAMI EC53	2020	ECG trunk cables and patient leadwires	原採認標準
147.	3 Cardiovascular 血管醫學	心臟	AAMI	ANSI/AAMI EC57	2020	Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Algorithms	
148.	3 Cardiovascular 心臟 血管醫學	AAMI	AAMI/IEC 60601-2-4	2018	Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators	原採認標準
149.	3 Cardiovascular 心臟 血管醫學	CEN	EN ISO 81060-1	2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type - CORR: July 31, 2012	原採認標準
150.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 5841-2	2014	Implants for Surgery - Cardiac Pacemakers - Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads	原採認標準
151.	3 Cardiovascular 心臟 血管醫學	IEC	IEC 60601-2-34	2024	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	原採認標準版本更新
152.	3 Cardiovascular 心臟 血管醫學	IEC	IEC 60601-2-47	2012	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	原採認標準
153.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 10555-4	2023	Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters	原採認標準
154.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 17475	2006	Corrosion of metals and alloys -- Electrochemical test methods -- Guidelines for conducting potentiostatic and potentiodynamic polarization measurements	原採認標準
155.	3 Cardiovascular 心臟	ISO	ISO 2248	1985	Packaging -- Complete, filled transport packages --	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	血管醫學				Vertical impact test by dropping	
156.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 25539-2	2020	Cardiovascular implants — Endovascular devices — Part 2: Vascular stents	原採認標準
157.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 25539-3	2024	Cardiovascular implants — Endovascular devicesPart 3: Vena cava filters	原採認標準版本更新
158.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 5841-3	2013	Implants for surgery -- Cardiac pacemakers -- Part 3: Low-profile connectors (IS-1) for implantable pacemakers	原採認標準
159.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 81060-1	2007	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type.	原採認標準
160.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 8318	2000	Packaging - Complete, Filled Transport Packages and Unit Loads - Sinusoidal Vibration Tests Using a Variable Frequency	原採認標準
161.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2082/F2082M	2023	Standard Test Method for Determination of Transformation Temperature of Nickel- Titanium Shape Memory Alloys by Bend and Free Recovery	原採認標準
162.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F3036	2021	Standard Guide for Testing Absorbable Stents	原採認標準
163.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 25539-1	2017	Cardiovascular implants— Endovascular devices— Part 1: Endovascular prostheses	原採認標準
164.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 5840-1	2025	Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements Amendment 1	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

165.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 5840-2	2025	Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes Amendment 1	原採認標準版本更新
166.	3 Cardiovascular 心臟 血管醫學	IEC	IEC 60601-2-27	2011	Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	原採認標準
167.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 15676	2016	Cardiovascular implants and artificial organs - Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)	原採認標準
168.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 5840-3	2025	Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques Amendment 1	原採認標準版本更新
169.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 7198	2016	Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches	原採認標準
170.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 12417-1	2024	Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements	原採認標準
171.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2004	2024	Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Analysis	
172.	3 Cardiovascular 心臟 血管醫學	IEC	IEC 60601-2-4	2018	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	原採認標準
173.	3 Cardiovascular 心臟 血管醫學	IEC	IEC 80601-2-30	2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	原採認標準
174.	3 Cardiovascular 心臟 血管醫學	IEC	IEC 80601-2-49	2024	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors	原採認標準版本更新
175.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 11070	2018	Sterile single-use intravascular introducers, dilators and guidewires	原採認標準
176.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 80601-2-61	2017	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	原採認標準
177.	3 Cardiovascular 心臟 血管醫學	AAMI	ANSI/AAMI EC12	2020	Disposable ECG electrodes	原採認標準
178.	3 Cardiovascular 心臟 血管醫學	AAMI	IEC 60601-2-25	2016	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.	原採認標準
179.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2081	2022	Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents	原採認標準
180.	3 Cardiovascular 心臟	ASTM	ASTM F1984	2025	Standard Practice for Testing for Whole Complement	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	血管醫學				Activation in Serum by Solid Materials	更新
181.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2079	2022	Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon Expandable Stents	原採認標準
182.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2394	2007	Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System	原採認標準
183.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 5910	2024	Cardiovascular implants and extracorporeal systems - Cardiac valve repair devices	原採認標準
184.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 81060-3	2022	Non-invasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type	原採認標準
185.	3 Cardiovascular 心臟 血管醫學	AAMI	AAMI/ISO 14117	2019	Active implantable medical devices— Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices.	原採認標準
186.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM G71-81	2024	Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes	原採認標準
187.	3 Cardiovascular 心臟 血管醫學	IEC	IEC 60601-2-31	2020	Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	原採認標準
188.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 14708-2	2019	Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

189.	3 Cardiovascular 血管醫學	心臟	ASTM	ASTM F138	2020	Standard Specification for Wrought 18 Chromium 14 Nickel 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	原採認標準
190.	3 Cardiovascular 血管醫學	心臟	ASTM	ASTM F2942	2019	Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents	原採認標準
191.	3 Cardiovascular 血管醫學	心臟	ISO	ISO 15674	2020	Cardiovascular implants and artificial organs - Hard-shell cardiectomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	原採認標準
192.	3 Cardiovascular 血管醫學	心臟	ISO	ISO 15675	2020	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters	原採認標準
193.	3 Cardiovascular 血管醫學	心臟	ISO	ISO 7199	2024	Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)	原採認標準版本更新
194.	3 Cardiovascular 血管醫學	心臟	ISO	ISO/TS 17137	2021	Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants	原採認標準
195.	3 Cardiovascular 血管醫學	心臟	ASTM	ASTM F1830	2019	Standard Practice for Collection and Preparation of Blood for Dynamic in vitro Evaluation of Hemolysis in Blood Pumps	原採認標準
196.	3 Cardiovascular 血管醫學	心臟	ASTM	ASTM F1841	2025	Standard Practice for Assessment of Hemolysis in Blood Pumps	原採認標準版本更新
197.	3 Cardiovascular 血管醫學	心臟	IEEE	IEEE Std 1708	2019	Standard for Wearable, Cuffless Blood Pressure Measuring Devices	原採認標準
198.	3 Cardiovascular 血管醫學	心臟	ISO	ISO/TS 81060-5	2020	Non-invasive sphygmomanometers - Part 5: Requirements for the repeatability and reproducibility	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					of NIBP simulators for testing of automated non-invasive sphygmomanometers	
199.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 14708-5	2020	Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices	原採認標準
200.	3 Cardiovascular 心臟 血管醫學	AAMI	AAMI TIR42	2021	Evaluation of Particulates Associated with Vascular Medical Devices	原採認標準
201.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 18193	2021	Cardiovascular implants and artificial organs - Cannulae for extracorporeal circulation	原採認標準
202.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F3172	2021	Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices	原採認標準
203.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F3067	2021	Standard Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents	原採認標準
204.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2606	2021	Standard Guide for Three-Point Bending of Balloon-Expandable Vascular Stents and Stent Systems	原採認標準
205.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2514	2021	Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading	原採認標準
206.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F3505	2021	Standard Test Method for Stent and Endovascular Prosthesis Kink Resistance	原採認標準
207.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 14708-6	2019	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					tachyarrhythmia (including implantable defibrillators)	
208.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 11658	2012	Cardiovascular implants and extracorporeal systems - Blood/tissue contact surface modifications for extracorporeal perfusion systems	原採認標準
209.	3 Cardiovascular 心臟 血管醫學	ASTM	ASTM F2477	2024	Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents and Endovascular Prostheses	原採認標準版本更新
210.	3 Cardiovascular 心臟 血管醫學	ANSI AAMI	ANSI AAMI PC76	2021	Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging	原採認標準
211.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 18242	2023	Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps Amendment 1: Worst-case conditions for testing	原採認標準
212.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 22679	2021	Cardiovascular implants - Transcatheter cardiac occluders	原採認標準
213.	3 Cardiovascular 心臟 血管醫學	ISO	ISO PAS 7020	2023	Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2	原採認標準
214.	3 Cardiovascular 心臟 血管醫學	ISO	ISO 25539-4	2021	Cardiovascular implants - Endovascular devices - Part 4: Application of ISO 17327-1 for coated endovascular devices	115 年度新增採認標準
215.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI	ADA Specification	1993	Resin-Based Filling Materials	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

			No.27			
216.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6360-3	2005	Dentistry -- Number coding system for rotary instruments -- Part 3: Specific characteristics of burs and cutters	原採認標準
217.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6360-4	2004	Dentistry -- Number coding system for rotary instruments -- Part 4: Specific characteristics of diamond instruments	原採認標準
218.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6360-6	2004	Dentistry -- Number coding system for rotary instruments -- Part 6: Specific characteristics of abrasive instruments	原採認標準
219.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6360-7	2006	Dentistry - Number coding system for rotary instruments - Part 7: Specific characteristics of mandrels and special instruments	原採認標準
220.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 13397-1	1995	Periodontal curettes, dental scalers and excavators -- Part 1: General requirements	原採認標準
221.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 13397-3	1996	Periodontal curettes, dental scalers and excavators -- Part 3: Dental scalers -- H-type	原採認標準
222.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 15854	2023	Dentistry - Casting and baseplate waxes	原採認標準
223.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6877	2021	Dentistry — Endodontic obturating materials	原採認標準
224.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9917-1	2025	Dentistry — Water-based cements Part 1: Acid-base cements	原採認標準版本 更新
225.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9168	2009	Dentistry -- Hose connectors for air driven dental	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	耳鼻喉科學				handpieces	
226.	4 Dental/ENT 牙科學/ 耳鼻喉科學	CEN	EN 1639	2009	Dentistry. Medical devices for dentistry. Instruments	原採認標準
227.	4 Dental/ENT 牙科學/ 耳鼻喉科學	CEN	EN 1640	2009	Dentistry. Medical devices for dentistry. Equipment	原採認標準
228.	4 Dental/ENT 牙科學/ 耳鼻喉科學	CEN	EN 1641	2009	Dentistry. Medical devices for dentistry. Materials	原採認標準
229.	4 Dental/ENT 牙科學/ 耳鼻喉科學	CEN	EN 1642	2011	Dentistry. Medical devices for dentistry. Dental implants	原採認標準
230.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 13397-2	2012	Dentistry — Periodontal curettes, dental scalers and excavators — Part 2: Periodontal curettes of Gr-type Amendment 1: Colour coding	原採認標準
231.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 21563	2021	Dentistry - Hydrocolloid impression materials	原採認標準
232.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 3107	2022	Dentistry — Zinc oxide-eugenol cements and non-eugenol zinc oxide cements	原採認標準
233.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6360-2	2011	Dentistry — Number coding system for rotary instruments — Part 2: Shapes	原採認標準
234.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6876	2012	Dentistry - Root canal sealing materials	原採認標準
235.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ADA	ANSI/ADA 96	2020	ANSI/ADA Standard No. 96—Dental Water-based Cements: 2012	原採認標準版本更新
236.	4 Dental/ENT 牙科學/ 耳鼻喉科學	AAMI	AAMI CI86	2017	Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					reporting	
237.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 10139-2	2016	Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use	原採認標準
238.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 14801	2016	Dentistry - Implants - Dynamic loading test for endosseous dental implants	原採認標準
239.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 22674	2022	Dentistry -- Metallic materials for fixed and removable restorations and appliances	原採認標準
240.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6360-1	2007	Dentistry — Number coding system for rotary instruments — Part 1: General characteristics	原採認標準
241.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6874	2015	Dentistry — Polymer-based pit and fissure sealants	原採認標準
242.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 7494-2	2022	Dentistry - Dental units - Part 2: Air, water, suction and wastewater systems	原採認標準
243.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 10139-1	2018	Dentistry - Soft lining materials for removable dentures - Part 1: Materials for short-term use	原採認標準
244.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 10477	2020	Dentistry -- Polymer-based crown and bridge materials	原採認標準
245.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 11137-3	2017	Sterilization of health care products — Radiation Part 3: Guidance on dosimetric aspects of development, validation and routine control	原採認標準
246.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 14457	2017	Dentistry -- Handpieces and motors	原採認標準
247.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 22112	2017	Dentistry - Artificial teeth for dental prostheses	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

248.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 7491	2000	Dental materials—Determination of colour stability	原採認標準
249.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 7494-1	2018	Dentistry — Stationary dental units and dental patient chairs Part 1: General requirements	原採認標準
250.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9917-2	2017	Dentistry - Water-based cements - Part 2: Resin-modified cements	原採認標準
251.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ASA	ASA S3.6	2018	American National Standard Specification for Audiometers	原採認標準
252.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 6872	2024	Dentistry - Ceramic materials	原採認標準版本更新
253.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9693	2019	Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems	原採認標準
254.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ASTM	ASTM F1088	2023	Standard Specification for Medical-Grade Beta-Tricalcium Phosphate Raw Material for Implantable Medical Devices	原採認標準
255.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 7405	2025	Dentistry — Evaluation of biocompatibility of medical devices used in dentistry	原採認標準版本更新
256.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 17730	2020	Dentistry - Fluoride varnishes	原採認標準
257.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 4049	2019	Dentistry -- Polymer-based restorative materials	原採認標準
258.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ASA	ASA S3.22	2024	Specification of Hearing Aid Characteristics	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

259.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 10650	2018	Dentistry — Powered polymerization activators	原採認標準
260.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ASA	ANSI ASA S3.7	2020	American National Standard Method for Coupler Calibration of Earphones	原採認標準
261.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 10271	2020	Dentistry - Corrosion test methods for metallic materials	原採認標準
262.	4 Dental/ENT 牙科學/ 耳鼻喉科學	IEC	IEC 80601-2-60	2019	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	原採認標準
263.	4 Dental/ENT 牙科學/ 耳鼻喉科學	IEC	IEC 60601-2-66	2019	Medical electrical equipment Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument system	原採認標準
264.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 10873	2021	Dentistry - Denture adhesives	原採認標準
265.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO/TR 22442-4	2010	Medical devices utilizing animal tissues and their derivatives — Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and validation assays for those processes	原採認標準
266.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 37	2020	Dental Abrasive Powders	原採認標準
267.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 87	2014	Dental Impression Trays	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

268.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 43	2020	Electrically Powered Dental Amalgamators	原採認標準
269.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 18556	2016	Dentistry - Intraoral spatulas	原採認標準
270.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 136	2022	Dentistry - External Tooth Bleaching Products	原採認標準
271.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ASA	ANSI ASA S3.22	2024	Specification of Hearing Aid Characteristics	原採認標準版本 更新
272.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 4823	2025	Dentistry — Elastomeric impression and bite registration materials	原採認標準版本 更新
273.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 139	2020	Dental Base Polymers	原採認標準
274.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 21606	2022	Dentistry - Elastomeric auxiliaries for use in orthodontics	原採認標準
275.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 22052	2020	Dentistry - Compressed air source equipment	原採認標準
276.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 13504	2012	Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment	原採認標準
277.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 14708-7	2019	Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear and auditory brainstem implant systems	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

278.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 10637	2018	Dentistry - Central suction source equipment	原採認標準
279.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9873	2019	Dentistry - Intra-oral mirrors	原採認標準
280.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 20126	2022	Dentistry - Manual toothbrushes - General requirements and test methods	原採認標準
281.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 41	2020	Evaluation of Biocompatibility of Medical Devices Used in Dentistry	原採認標準
282.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9333	2022	Dentistry - Brazing materials	原採認標準
283.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9687	2015	Dentistry - Graphical symbols for dental equipment	原採認標準
284.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 21531	2009	Dentistry - Graphical symbols for dental instruments	原採認標準
285.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 78	2022	Dentistry - Endodontic Obturating Materials	原採認標準版本更新
286.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 15	2021	Artificial Teeth for Dental Prostheses	原採認標準
287.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ASA	ANSI ASA S3.35	2025	Standard Method of Measurement of Performance Characteristics of Hearing Aids Under Simulated Real-Ear Working Conditions	原採認標準版本更新
288.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 27020	2019	Dentistry - Brackets and tubes for use in orthodontics	原採認標準
289.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI	ANSI ADA	2020	Orthodontic Brackets and Tubes	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	耳鼻喉科學	ADA	Standard No.100			
290.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 24234	2021	Dentistry - Dental Amalgam	原採認標準
291.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 8325	2023	Dentistry - Test methods for rotary instruments	原採認標準
292.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 20749	2023	Dentistry - Pre-capsulated dental amalgam	原採認標準
293.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 117	2022	Dentistry - Fluoride Varnishes	原採認標準
294.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 13402	2025	Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure	原採認標準版本 更新
295.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 23450	2021	Dentistry - Intraoral camera	原採認標準
296.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 18675	2022	Dentistry - Machinable ceramic blanks	原採認標準
297.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 5139	2023	Dentistry - Polymer-based composite machinable blanks	原採認標準
298.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO TS 16506	2017	Dentistry - Polymer-based luting materials containing adhesive components	原採認標準
299.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 20795-1	2013	Dentistry- Base polymers- Part 1: Denture base polymers	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

300.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 46	2016	Dental Patient Chair	115 年度新增採 認標準
301.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 47-1	2021	Stationary Dental Units and Patient Chairs-Part 1: General Requirements	115 年度新增採 認標準
302.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 47-2	2021	Stationary Dental Units and Patient Chairs-Part 2: Air Water Suction and Wastewater Systems	115 年度新增採 認標準
303.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 105	2024	Elastomeric Auxiliaries for Use in Orthodontics	115 年度新增採 認標準
304.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 186	2024	Dentistry - Polymer-based Machinable Blanks	115 年度新增採 認標準
305.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 187	2024	Dentistry - Dental CAD/CAM Machinable Ceramic Blanks	115 年度新增採 認標準
306.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 9680	2021	Dentistry - Operating lights	115 年度新增採 認標準
307.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 89	2023	Dentistry - Dental Operating Lights	115 年度新增採 認標準
308.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 57	2021	Endodontic Sealing Materials	115 年度新增採 認標準
309.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI	ANSI ADA	2020	Endodontic Instruments - Auxillary	115 年度新增採 認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	耳鼻喉科學	ADA	Standard No. 63			認標準
310.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 28399	2021	Dentistry - External tooth bleaching products	115 年度新增採 認標準
311.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 206	2024	Implantable Materials for Bone Filling and Augmentation in Oral and Maxillofacial Surgery - Contents of a Technical File	115 年度新增採 認標準
312.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 3630-4	2023	Dentistry - Endodontic instruments - Part 4: Auxiliary instruments	115 年度新增採 認標準
313.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 11143	2008	Dentistry - Amalgam separators	115 年度新增採 認標準
314.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 108	2009	Amalgam Separators	115 年度新增採 認標準
315.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 11499	2014	Dentistry - Single-use cartridges for local anaesthetics	115 年度新增採 認標準
316.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 190	2020	Single-Use Dental Cartridges for Local Anesthetics	115 年度新增採 認標準
317.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 18397	2016	Dentistry - Powered scaler	115 年度新增採 認標準
318.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ANSI ADA	ANSI ADA Standard No. 157	2020	Powered Dental Scaler Handpieces and Tips	115 年度新增採 認標準
319.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 20608	2018	Dentistry - Powder jet handpieces and powders	115 年度新增採

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	耳鼻喉科學					認標準
320.	4 Dental/ENT 牙科學/ 耳鼻喉科學	ISO	ISO 22683	2022	Dentistry - Rotational adaptability test between implant body and implant abutment in dental implant systems	115 年度新增採認標準
321.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 10012	2003	Measurement management systems — Requirements for measurement processes and measuring equipment	原採認標準
322.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS14991	2006	命名—用於醫療器材法規管理資料交換之命名系統的規格	原採認標準
323.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS14989	2006	醫療器材風險管理	原採認標準
324.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS14990	2006	醫療器材—用於醫療器材標識、標示與資訊之符號	原採認標準
325.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 14155	2020	Clinical investigation of medical devices for human subjects -- Good clinical practice	原採認標準
326.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	AAMI TIR69	2020	Risk management of radio-frequency wireless coexistence for medical devices and systems	原採認標準
327.	5 General I (QS/RM) 通用(品質管理系統/風	EN	EN 45502-1	2015	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety,	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	險管理)				marking and for information to be provided by the manufacturer	
328.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 13485	2016	Medical devices — Quality management systems — Requirements for regulatory purposes	原採認標準
329.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 15223-1	2025	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific	原採認標準版本更新
330.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 16061	2021	Instruments for use in association with non-active surgical implants — General requirements	原採認標準
331.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 80369-6	2025	Small bore connectors for liquids and gases in healthcare applications Part 6: Connectors for neural applications	原採認標準版本更新
332.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	AAMI HE75	2018	Human factors engineering - Design of medical devices	原採認標準
333.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	IEC 80369-5	2021	Small-bore connectors for liquids and gases in healthcare applications—Part 5: Connectors for limb cuff inflation applications	原採認標準
334.	5 General I (QS/RM)	ISO	ISO 14971	2019	Medical devices -- Application of risk management to	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	通用(品質管理系統/風險管理)				medical devices	
335.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO/TR 24971	2020	Medical devices — Guidance on the application of ISO 14971	原採認標準
336.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	IEC 62366-1	2020	Medical devices – Part 1: Application of usability engineering to medical devices	原採認標準
337.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 80369-3	2019	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications	原採認標準
338.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 7010	2025	Graphical symbols — Safety colours and safety signs — Registered safety signs Amendment 9	原採認標準版本更新
339.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	CNS	CNS 62366-1	2021	"醫療器材—第 1 部：醫療器材可用性工程之應用 Medical devices – Part 1: Application of usability engineering to medical devices	原採認標準
340.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ASME	ASME V&V 10	2019	Standard for Verification and Validation in Computational Solid Mechanics	原採認標準
341.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	IEC TR 60878	2022	Graphical symbols for electrical equipment in medical practice	原採認標準
342.	5 General I (QS/RM)	ASTM	ASTM D4332	2022	Standard Practice for Conditioning Containers	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	通用(品質管理系統/風險管理)				Packages or Packaging Components for Testing	
343.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 18250-3	2018	Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 3: Enteral application	原採認標準
344.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ASME	ASME V&V 20	2021	Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer	原採認標準
345.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	AAMI	AAMI TIR66	2020	Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms	原採認標準
346.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	ISO	ISO 780	2015	Packaging - Distribution packaging - Graphical symbols for handling and storage of packages	原採認標準
347.	5 General I (QS/RM) 通用(品質管理系統/風險管理)	IEC	IEC 60417	2025	Graphical symbols for use on equipment	115 年度新增採認標準
348.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8536-5	2004	Infusion equipment for medical use Part 5: Burette infusion sets for single use, gravity feed	原採認標準
349.	6 General Plastic	CNS	CNS 14775	2022	醫用面罩材料細菌過濾效率試驗法—使用金黃色	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				葡萄球菌生物氣霧 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	
350.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 11608-4	2022	Needle-based injection systems for medical use — Requirements and test methods Part 4: Needle-based injection systems containing electronics	原採認標準
351.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 21649	2023	Needle-free injectors for medical use – Requirements and test methods	原採認標準
352.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8362-3	2001	Injection containers and accessories -- Part 3: Aluminium caps for injection vials	原採認標準
353.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8362-7	2006	Injection containers and accessories – Part 7: Injection caps made of aluminiumplastics combinations without overlapping plastics part	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

354.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 4397	1999	脫脂紗布	原採認標準
355.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 15036-1	2006	用於人類血液和血液成品塑膠可折疊之容器—第1部：慣用容器（血袋）	原採認標準
356.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 13460	1994	電刀裝置	原採認標準
357.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14624-2	2002	醫療用輸液設備—第二部份：點滴瓶瓶塞	原採認標準
358.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及	CNS	CNS 14624-3	2002	醫療用輸液設備—第三部份：點滴瓶鋁蓋	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	個人使用裝置					
359.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 15883-2	2024	Washer-disinfectors Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices	原採認標準版本更新
360.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 15883-3	2024	Washer-disinfectors -- Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	原採認標準版本更新
361.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 15883-5	2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	原採認標準
362.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 15042	2007	間歇性測定患者體溫之紅外線體溫計	原採認標準
363.	6 General Plastic Surgery/General Hospital 一般及整形	CNS	CNS 15043	2007	間歇性測定患者體溫之電子式體溫計	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	外科手術/一般醫院及個人使用裝置					
364.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 15044	2007	體溫計探針護套	原採認標準
365.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 15212-3	2008	電子體溫計－第 3 部：具最大值（非預測性與預測性）裝置之小型電子體溫計的性能	原採認標準
366.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 15212-4	2008	電子體溫計－第 4 部：用於連續量測之電子體溫計的性能	原採認標準
367.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 15212-5	2008	電子體溫計－第 5 部：紅外線耳溫計（具最大值裝置）的性能	原採認標準
368.	6 General Plastic Surgery/General	CNS	CNS 15226	2009	單次使用之無菌橡膠手套－規格	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置					
369.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	CNS	CNS 15227	2009	單次使用之醫用檢驗手套－第 1 部：以乳膠或橡 膠溶液製成之手套規格	原採認標準
370.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8536-2	2023	Infusion equipment for medical use -- Part 2: Closures for infusion bottles	原採認標準
371.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8536-3	2022	Infusion equipment for medical use -- Part 3: Aluminium caps for infusion bottles	原採認標準
372.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8536-7	2009	Infusion equipment for medical use -- Part 7: Caps made of aluminium-plastics combinations for infusion bottles	原採認標準
373.	6 General Plastic	ISO	ISO 8362-6	2010	Injection containers and accessories -- Part 6: Caps	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				made of aluminium-plastics combinations for injection vials	
374.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	OIML	OIML R115	2010	Clinical electrical thermometers with maximum device	原採認標準
375.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	AAMI	AAMI PB70	2022	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	原採認標準
376.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F1671/F1671M	2025	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System	原採認標準版本更新
377.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F2172	2002	Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

378.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F86	2021	Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	原採認標準
379.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14755	2022	拋棄式防塵口罩 (Disposable dust respirators)	原採認標準
380.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14778	2003	防護衣詞彙 (Terminology relating to protective clothing) (IDE ASTM F1494-01)	原採認標準
381.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14798	2004	拋棄式醫用防護衣—性能要求(The performance requirements for disposable medical protective clothing)	原採認標準
382.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及	CNS	CNS 14799	2004	防護衣材料對合成血液穿透阻力試驗法 (Method of test for resistance of materials used in protective clothing to penetration by synthetic blood) (IDE ASTM F1670-98)	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	個人使用裝置					
383.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14800	2004	使用 Phi-X174 噬菌體穿透力之試驗系統供防護衣材料對血液媒介病原穿透阻力的試驗法(Method of test for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system) (IDE AATCC 42-2000)	原採認標準
384.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14801	2004	防護衣材料防水性試驗法－衝擊穿透試驗(Method of test for water resistance of material used in protective clothing (Impact penetration test))	原採認標準
385.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 15554	2012	醫電設備電性安全－第 2-52 部：醫護床基本安全及必要性能的特殊要求 (Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds) (IDE IEC 60601-2-52:2010)	原採認標準
386.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-24	2012	Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers	原採認標準
387.	6 General Plastic Surgery/General	IEC	IEC 60601-2-41	2021	Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置				essential performance of surgical luminaires and luminaires for diagnosis	
388.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 10555-3	2013	Intravascular catheters -- Sterile and single-use catheters -- Part 3: Central venous catheters	原採認標準
389.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 10555-5	2013	Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters	原採認標準
390.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 11608-2	2022	Needle-based injection systems for medical use — Requirements and test methods Part 2: Double-ended pen needles	原採認標準
391.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 11608-3	2022	Needle-based injection systems for medical use — Requirements and test methods Part 3: Containers and integrated fluid paths	原採認標準
392.	6 General Plastic	ISO	ISO 7740	1985	Instruments for surgery, scalpels with detachable	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置				blades, fitting dimensions	
393.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8362-4	2011	Injection containers and accessories -- Part 4: Injection vials made of moulded glass	原採認標準
394.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8536-1	2011	Infusion equipment for medical use — Part 1: Infusion glass bottles	原採認標準
395.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 9187-1	2010	Injection equipment for medical use -- Part 1: Ampoules for injectables	原採認標準
396.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 10282	2023	Single-use sterile rubber surgical gloves - Specification	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

397.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D7160	2023	Standard Practice for Determination of Expiration Dating for Medical Gloves	原採認標準
398.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D7161	2023	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions	原採認標準
399.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F2051	2021	Standard Specification for Implantable Saline Filled Breast Prosthesis	原採認標準
400.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	EN	EN 1865-1	2021	Patient handling equipment used in road ambulances Part 1: General stretcher systems and patient handling equipmen	原採認標準
401.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及	EN	EN 1865-2	2024	Patient handling equipment used in ambulances - Part 2: Power assisted stretcher	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	個人使用裝置					
402.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	EN	EN 1865-3	2016	Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	原採認標準
403.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	EN	EN 455-2	2024	Medical gloves for single use. Requirements and testing for physical properties	原採認標準
404.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	EN	EN 455-3	2023	Medical gloves for single use. Requirements and testing for biological evaluation	原採認標準
405.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-20	2023	Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	原採認標準版本更新
406.	6 General Plastic Surgery/General Hospital 一般及整形	IEC	IEC 60601-2-21	2023	Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	外科手術/一般醫院及個人使用裝置					
407.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-46	2023	Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables	原採認標準
408.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-50	2023	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	原採認標準版本更新
409.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-52	2015	Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	原採認標準
410.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-35	2023	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	原採認標準
411.	6 General Plastic Surgery/General	ISO	ISO 1135-4	2025	Transfusion equipment for medical use Part 4: Transfusion sets for single use, gravity feed	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置					
412.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 11608-5	2022	Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions	原採認標準
413.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 15883-1	2024	Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests	原採認標準版本 更新
414.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 3826-4	2015	Plastics collapsible containers for human blood and blood components Part 4: Aphaeresis blood bag systems with integrated features	原採認標準
415.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 6009	2016	Hypodermic needles for single use - Colour coding for identification	原採認標準
416.	6 General Plastic	ISO	ISO 7864	2016	Sterile hypodermic needles for single use —	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置				Requirements and test methods	
417.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 80369-20	2024	Small-bore connectors for liquids and gases in healthcare applications Part 20: Common test methods	原採認標準版本 更新
418.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8362-2	2024	Injection containers and accessories - Part 2: Closures for injection vials	原採認標準
419.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8362-5	2016	Injection containers and accessories - Part 5: Freeze drying closures for injection vials	原採認標準
420.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 8536-10	2015	Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment (ISO 8536-10:2015)	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

421.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8536-11	2015	Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment (ISO 8536-11:2015)	原採認標準
422.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8536-6	2025	Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles	原採認標準版本更新
423.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8536-8	2015	Infusion equipment for medical use Part 8: Infusion sets for single use with pressure infusion apparatus	原採認標準
424.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8536-9	2015	Infusion equipment for medical use Part 9: Fluid lines for single use with pressure infusion equipment	原採認標準
425.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及	ISO	ISO 8537	2016	Sterile single-use syringes, with or without needle, for insulin	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	個人使用裝置					
426.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 9626	2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	原採認標準
427.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F703	2021	Standard Specification for Implantable Breast Prostheses	原採認標準
428.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CNS	CNS 14774	2022	醫用面(口)罩	原採認標準
429.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-19	2023	Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	原採認標準版本更新
430.	6 General Plastic Surgery/General Hospital 一般及整形	IEC	IEC 80601-2-59	2023	Medical electrical equipment -- Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	外科手術/一般醫院及個人使用裝置				febrile temperature screening	
431.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 10555-1	2023	Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements	原採認標準
432.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 7886-1	2017	Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use	原採認標準
433.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 21171	2006	Medical gloves Determination of removable surface powder	原採認標準
434.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F881	2016	Standard Specification for Silicone Elastomer Facial Implants	原採認標準
435.	6 General Plastic Surgery/General	ASTM	ASTM F1441	2016	Standard Specification for Soft-Tissue Expander Devices	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置					
436.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM F754	2024	Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders	原採認標準版本 更新
437.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM E1104	2023	Standard Specification for Clinical Thermometer Probe Covers and Sheaths	原採認標準
438.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM E1965	2023	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	原採認標準
439.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	AAMI	AAMI BP22	2016	Blood pressure transducers	原採認標準
440.	6 General Plastic	ASTM	ASTM D6124	2022	Standard Test Method for Residual Powder on	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				Medical Gloves	
441.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D6355	2022	Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves	原採認標準
442.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM E1112	2018	Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature	原採認標準
443.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F1670 / F1670M	2024	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	原採認標準
444.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 80601-2-56	2018	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

445.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 11193-1	2020	Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution	原採認標準
446.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CEN	EN 13795-1	2025	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	原採認標準版本更新
447.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CEN	EN 13795-2	2025	Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits	原採認標準版本更新
448.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F1580	2019	Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants	原採認標準
449.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及	ASTM	ASTM F2213	2017	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	個人使用裝置					
450.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F75	2023	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	原採認標準
451.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D6499	2024	Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	原採認標準
452.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D7169	2023	Standard Test Method for Boiling Point Distribution of Samples with Residues Such as Crude Oils and Atmospheric and Vacuum Residues by High Temperature Gas Chromatography	原採認標準
453.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	EN	EN 14683	2025	Medical face masks - Requirements and test methods	原採認標準版本更新
454.	6 General Plastic Surgery/General Hospital 一般及整形	ISO	ISO 8362-1	2018	Injection containers and accessories - Part 1: Injection vials made of glass tubing	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	外科手術/一般醫院及個人使用裝置					
455.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 7886-2	2020	Sterile Hypodermic Syringes for Single Use - Part 2: Syringes for use with Power-Driven Syringe Pumps	原採認標準
456.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 7886-3	2020	Sterile hypodermic syringes for single use -- Part 3: Auto-disable syringes for fixed-dose immunization	原採認標準
457.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	CEN	EN 455-1	2024	Medical gloves for single use —Part 1: Requirements and testing for freedom from holes	原採認標準
458.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D3577	2023	Standard Specification for Rubber Surgical Gloves	原採認標準
459.	6 General Plastic Surgery/General	ASTM	ASTM D3578	2023	Standard Specification for Rubber Examination Gloves	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置					
460.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM D5151	2023	Standard Test Method for Detection of Holes in Medical Gloves	原採認標準
461.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM D6978	2023	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	原採認標準
462.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM F2182	2020	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	原採認標準
463.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM F2503	2023	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	原採認標準
464.	6 General Plastic	ASTM	ASTM F899	2023	Standard Specification for Wrought Stainless Steels	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				for Surgical Instruments	
465.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 8536-4	2019	Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed	原採認標準
466.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM A908	2024	Standard Specification for Stainless Steel Needle Tubing	原採認標準版本更新
467.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D5250	2023	Standard Specification for Poly(vinyl chloride) Gloves for Medical Application	原採認標準
468.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F2710	2019	Standard Consumer Safety Performance Specification for Commercial Cribs	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

469.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D6319	2023	Standard Specification for Nitrile Examination Gloves for Medical Application	原採認標準
470.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D6977	2023	Standard Specification for Polychloroprene Examination Gloves for Medical Application	原採認標準
471.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM D7103	2023	Standard Guide for Assessment of Medical Gloves	原採認標準
472.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	AAMI	AAMI TIR38	2019	Medical device safety assurance case guidance	原採認標準
473.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及	EN ISO	EN ISO 15747	2019	Plastic containers for intravenous injections	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	個人使用裝置					
474.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F2407/F2407M	2023	Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	原採認標準
475.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 22610	2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration	原採認標準
476.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	AAMI	AAMI TIR101	2021	Fluid delivery performance testing for infusion pumps	原採認標準
477.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 11608-1	2022	Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems	原採認標準
478.	6 General Plastic Surgery/General Hospital 一般及整形	ISO	ISO 11040-4	2024	Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	外科手術/一般醫院及個人使用裝置					
479.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 11608-6	2022	Needle-based injection systems for medical use - Requirements and test methods - Part 6: On-body delivery	原採認標準
480.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ANSI AAMI	ANSI AAMI CN27	2021	General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications	原採認標準
481.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F2100	2025	Standard Specification for Performance of Materials Used in Medical Face Masks	原採認標準版本更新
482.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ANSI AAMI	ANSI AAMI PB70	2022	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	原採認標準
483.	6 General Plastic Surgery/General	ASTM	ASTM F739	2020	Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置				Conditions of Continuous Contact	
484.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM F1670/F1670M	2024	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	原採認標準版本 更新
485.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ISO	ISO 7886-4	2018	Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature	原採認標準
486.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM F3352/F3352M	2023	Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities	原採認標準
487.	6 General Plastic Surgery/General Hospital 一般及整形 外科手術/一般醫院及 個人使用裝置	ASTM	ASTM F2101	2025	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials Using a Biological Aerosol of Staphylococcus aureus	原採認標準版本 更新
488.	6 General Plastic	ISO	ISO 10555-6	2019	Intravascular catheters — Sterile and single-use	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置				catheters — Part 6: Subcutaneous implanted ports Amendment 1	更新
489.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 20698	2018	Catheter systems for neuraxial application - Sterile and single-use catheters and accessories	原採認標準
490.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F3502	2025	Standard Specification for Barrier Face Coverings	原採認標準版本更新
491.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 10535	2021	Assistive products - Hoists for the transfer of disabled persons - Requirements and test methods	原採認標準
492.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 63045	2020	Ultrasonics - Non-focusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

493.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 23217	2024	Injection systems for self-administration by paediatric patients - Requirements and guidelines for design	原採認標準
494.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 60601-2-2	2023	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	原採認標準
495.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 23908	2024	Sharps injury protection - Sharps protection mechanisms for single-use needles introducers for catheters and needles used for blood testing monitoring sampling and medical substance administration - Requirements and test methods	115 年度新增採認標準
496.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	IEC	IEC 80601-2-77	2023	Medical electrical equipment - Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT	115 年度新增採認標準
497.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及	ISO	ISO 14607	2024	Non-active surgical implants - Mammary implants - Specific requirements	115 年度新增採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	個人使用裝置					
498.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ISO	ISO 16571	2024	Systems for evacuation of plume generated by medical device	115 年度新增採認標準
499.	6 General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置	ASTM	ASTM F1862/F1862M	2024	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	115 年度新增採認標準
500.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H15	2000	Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard	原採認標準
501.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M15	2000	Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline	原採認標準
502.	7 In Vitro Diagnostics 體外診斷醫療器材	CEN	EN 13612	2002	Performance evaluation of in vitro diagnostic medical devices	原採認標準
503.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H56	2006	Body fluid analysis for cellular composition	原採認標準
504.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI I/LA02	2006	Quality assurance of laboratory tests for autoantibodies to nuclear antigens: (1)Indirect fluorescence assay for microscopy and (2) Microtiter enzyme immunoassay methods	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

505.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C39	2000	A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard	原採認標準
506.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C45	2004	Measurement of Free Thyroid Hormones; - Approved Guideline	原採認標準
507.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT01	2006	Point-of-Care Connectivity; Approved Standard	原採認標準
508.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H57	2008	Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline	原採認標準
509.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C61	1998	Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard	原採認標準
510.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C37	1999	Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline	原採認標準
511.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP06	2020	Evaluation of the Linearity of Quantitative Measurement Procedures	原採認標準
512.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M26	1999	Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline	原採認標準
513.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM13	2020	Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

514.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M39	2022	Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data	原採認標準
515.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM09	2023	Human Genetic and Genomic Testing Using Traditional and High-Throughput Nucleic Acid Sequencing Methods	原採認標準
516.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP10	2024	Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline	原採認標準
517.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H21	2024	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline	原採認標準
518.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI I/LA21	2008	Clinical Evaluation of Immunoassays; Approved Guideline	原採認標準
519.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H20	2007	Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard	原採認標準
520.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H42	2007	Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline	原採認標準
521.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H43	2007	Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline	原採認標準
522.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H44	2004	Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry and Supravital Dyes); Approved Guideline	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

523.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M28	2005	Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline	原採認標準
524.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP12	2023	Evaluation of Qualitative, Binary Output Examination Performance	原採認標準
525.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP18	2009	Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline	原採認標準
526.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C46	2009	Blood Gas and pH Analysis and Related Measurements; Approved Guideline	原採認標準
527.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H26	2010	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard	原採認標準
528.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M22	2004	Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard	原採認標準
529.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM11	2007	Molecular Methods for Bacterial Strain Typing; Approved Guideline	原採認標準
530.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C43	2010	Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline	原採認標準
531.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H54	2005	Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline	原採認標準
532.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C40	2024	Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline	原採認標準
533.	7 In Vitro Diagnostics	CLSI	CLSI EP17	2012	Evaluation of Detection Capability for Clinical	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	體外診斷醫療器材				Laboratory Measurement Procedures; Approved Guideline	
534.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI GP40	2024	Preparations and Testing of Reagent Water in the Medical Laboratory	原採認標準版本更新
535.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI GP42	2020	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard	原採認標準
536.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP24	2011	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline	原採認標準
537.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP28	2010	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline	原採認標準
538.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI GP39	2010	Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard	原採認標準
539.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI I/LA25	2011	Maternal Serum Screening; Approved Standard	原採認標準
540.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM01	2023	Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline	原採認標準
541.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM05	2012	Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline	原採認標準
542.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM06	2010	Quantitative Molecular Methods for Infectious Diseases; Approved Guideline	原採認標準
543.	7 In Vitro Diagnostics	CLSI	CLSI MM14	2025	Design of Molecular Proficiency Testing/External	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	體外診斷醫療器材				Quality Assessment; Approved Guideline	更新
544.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT12	2013	Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline	原採認標準
545.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT14	2020	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline	原採認標準
546.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI QMS06	2025	Quality Management System: Continual Improvement	原採認標準版本更新
547.	7 In Vitro Diagnostics 體外診斷醫療器材	CNS	CNS 15449-2-101	2014	量測、控制及實驗室使用電氣設備安全規定－第2-101 部:體外診斷(IVD)醫用設備之個別規定 Safe requirements for electrical for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IDT: IEC 61010-2-101:2002)	原採認標準
548.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI GP34	2010	Validation and Verfication of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guidance	原採認標準
549.	7 In Vitro Diagnostics 體外診斷醫療器材	EN	EN 13532	2002	General requirements for in vitro diagnostic medical devices for self-testing	原採認標準
550.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 15197	2013	In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	原採認標準
551.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI AUTO11	2024	Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

552.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C24	2016	Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions	原採認標準
553.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C62	2022	Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline	原採認標準
554.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP05	2014	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline	原採認標準
555.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP14	2022	Evaluation of Commutability of Processed Samples	原採認標準
556.	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61326-2-6	2025	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment	原採認標準版本更新
557.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 15193	2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures	原採認標準
558.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 15194	2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation	原採認標準
559.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-1	2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements	原採認標準
560.	7 In Vitro Diagnostics	ISO	ISO 18113-2	2022	In vitro diagnostic medical devices — Information	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	體外診斷醫療器材				supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use	
561.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-3	2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use	原採認標準
562.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-4	2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing	原採認標準
563.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 18113-5	2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing	原採認標準
564.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP15	2019	User Verification of Precision and Estimation of Bias	原採認標準
565.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP19	2022	A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures	原採認標準
566.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP21	2025	Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures	原採認標準版本 更新
567.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI I/LA20	2016	Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities	原採認標準
568.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM03	2015	Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline	原採認標準
569.	7 In Vitro Diagnostics	CLSI	CLSI MM21	2015	Genomic Copy Number Microarrays for	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	體外診斷醫療器材				Constitutional Genetic and Oncology Applications	
570.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT04	2016	Essential Tools for Implementation and Management of a Point-of-Care Testing Program	原採認標準
571.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT13	2018	Glucose Monitoring in Settings Without Laboratory Support	原採認標準
572.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M36	2004	Clinical Use and Interpretation of Serologic Tests for <i>Toxoplasma gondii</i>	原採認標準
573.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M62	2020	Performance Standards for Susceptibility Testing of <i>Mycobacteria</i> <i>Nocardia</i> spp. and other Aerobic Actinomycetes	原採認標準
574.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI POCT05	2020	Performance Metrics for Continuous Interstitial Glucose Monitoring	原採認標準
575.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 17822	2020	In vitro diagnostic test systems — Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens — Laboratory quality practice guide	原採認標準
576.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI C49	2018	Analysis of Body Fluids in Clinical Chemistry; Approved Guideline	原採認標準
577.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP09	2018	Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline	原採認標準
578.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M27	2017	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts	原採認標準
579.	7 In Vitro Diagnostics	CLSI	CLSI VET01	2024	Performance Standards for Antimicrobial Disk and	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	體外診斷醫療器材				Dilution Susceptibility Tests for Bacteria Isolated From Animals	
580.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP07	2018	Interference Testing in Clinical Chemistry	原採認標準
581.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M23	2023	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters	原採認標準
582.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M02	2024	Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard	原採認標準
583.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M07	2024	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard	原採認標準
584.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M11	2018	Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard	原採認標準
585.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M24	2018	Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard	原採認標準
586.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 6710	2017	Single-use containers for human venous blood specimen collection	原採認標準
587.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M45	2016	Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline	原採認標準
588.	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61010-2-101	2018	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101: Particular Requirements for in Vitro	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Diagnostic (IVD) Medical Equipment	
589.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI QMS24	2016	Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality	原採認標準
590.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM17	2018	Validation and Verification of Multiplex Nucleic Acid Assays	原採認標準
591.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM23	2025	Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms)	原採認標準版本更新
592.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 17511	2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	原採認標準
593.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 20776-1	2019	Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Broth micro-dilution reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases	原採認標準
594.	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61010-1	2019	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements	原採認標準
595.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO/TS 20914	2019	Medical laboratories - Practical guidance for the estimation of measurement uncertainty	原採認標準
596.	7 In Vitro Diagnostics	CLSI	CLSI EP35	2025	Assessment of Equivalence or Suitability of	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	體外診斷醫療器材				Specimen Types for Medical Laboratory Measurement Procedures	更新
597.	7 In Vitro Diagnostics 體外診斷醫療器材	CEN ISO	EN ISO 23640	2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents	原採認標準
598.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 17099	2024	Radiological protection - Performance criteria for laboratories using the cytokinesis block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry	原採認標準
599.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP39	2021	A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests	原採認標準
600.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 19238	2023	Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics	原採認標準
601.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP25	2023	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.	原採認標準
602.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M100	2025	Performance Standards for Antimicrobial Susceptibility Testing	原採認標準版本更新
603.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI NBS01	2021	Dried Blood Spot Specimen Collection for Newborn Screening	原採認標準
604.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP27	2022	Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures	原採認標準
605.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M27M44S	2022	Performance Standards for Antifungal Susceptibility Testing of Yeasts	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

606.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H47	2023	One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test	原採認標準版本更新
607.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI MM24	2021	Molecular Methods for Genotyping and Strain Typing of Infectious Organisms	原採認標準
608.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI H62	2021	Validation of Assays Performed by Flow Cytometry	原採認標準
609.	7 In Vitro Diagnostics 體外診斷醫療器材	ISO	ISO 20916	2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice	原採認標準
610.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI PRE04	2023	Handling, Transport, Processing, and Storage of Blood Specimens for Routine Laboratory Examinations	原採認標準
611.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI I/LA28	2011	Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays	原採認標準
612.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	M29	2014	Protection of Laboratory Workers From Occupationally Acquired Infections	原採認標準
613.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	MM18	2018	Interpretive Criteria for Identification of Bacteria and Fungi by Targeted DNA Sequencing	原採認標準
614.	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 60068-2-64	2019	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	原採認標準
615.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP34	2018	Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking	115 年度新增採認標準
616.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP37	2018	Supplemental Tables for Interference Testing in Clinical Chemistry	115 年度新增採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

617.	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61010-2-010	2019	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials	115 年度新增採 認標準
618.	7 In Vitro Diagnostics 體外診斷醫療器材	IEC	IEC 61010-2-081	2019	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	115 年度新增採 認標準
619.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI EP06-EG	2024	Developer Validation of Linearity Establishment Guide	115 年度新增採 認標準
620.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M38M51S	2022	Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi	115 年度新增採 認標準
621.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M47	2022	Principles and Procedures for Blood Cultures	115 年度新增採 認標準
622.	7 In Vitro Diagnostics 體外診斷醫療器材	CLSI	CLSI M24S	2023	Performance Standards for Susceptibility Testing of Mycobacteria Nocardia spp. and Other Aerobic Actinomycetes	115 年度新增採 認標準
623.	8 Materials 材料	ISO	ISO 9073-10	2003	Textiles -- Test methods for nonwovens -- Part 10: Lint and other particles generation in the dry state	原採認標準
624.	8 Materials 材料	ISO	ISO 5832-6	2022	Implants for surgery -- Metallic materials -- Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	原採認標準
625.	8 Materials 材料	ISO	ISO 5832-5	2022	Implants for surgery — Metallic materials Part 5: Wrought cobalt-chromium-tungsten-nickel	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

626.	8 Materials 材料	ISO	ISO 16428	2005	Implants for surgery - Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices	原採認標準
627.	8 Materials 材料	CNS	CNS 13382-1	2004	外科體內植入物－金屬材料－鍛造不鏽鋼	原採認標準
628.	8 Materials 材料	CNS	CNS 13382-2	2004	外科體內植入物－金屬材料－鍛造鈷－鉻－鎢－鎳合金	原採認標準
629.	8 Materials 材料	CNS	CNS 13382-3	2004	外科體內植入物－金屬材料－鍛造鈷－鎳－鉻－鉬－鎢－鐵 合金	原採認標準
630.	8 Materials 材料	CNS	CNS 13382-4	2004	外科體內植入物－金屬材料－鍛造鈷－鎳－鉻－鉬合金	原採認標準
631.	8 Materials 材料	CNS	CNS 13382-5	2004	外科體內植入物－金屬材料－鈦金屬	原採認標準
632.	8 Materials 材料	CNS	CNS 13382-6	2004	外科體內植入物－金屬材料－鑄造鈷-鉻-鉬合金	原採認標準
633.	8 Materials 材料	CNS	CNS 13382-7	2004	外科體內植入物－金屬材料－鍛造鈦－6 鋁－4 鈮合金	原採認標準
634.	8 Materials 材料	CNS	CNS 13382-8	2004	外科體內植入物－金屬材料－可鍛及冷作加工鈷－鉻－鎳－鉬－鐵合金	原採認標準
635.	8 Materials 材料	CEN	EN ISO 9073-3	2023	Nonwovens - Test methods - Part 3: Determination of tensile strength and elongation at break using the strip method (ISO 9073-3:2023, Corrected version 2025-05)	原採認標準版本更新
636.	8 Materials 材料	ASTM	ASTM F1713	2021	Standard Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130)	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

637.	8 Materials 材料	ASTM	ASTM F562	2022	Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)	原採認標準
638.	8 Materials 材料	ISO	ISO 139	2011	Textiles -- Standard atmospheres for conditioning and testing	原採認標準
639.	8 Materials 材料	ASTM	ASTM D3772	2021	Standard Specification for Industrial Rubber Finger Cots	原採認標準
640.	8 Materials 材料	ASTM	ASTM F1185	2023	Standard Specification for Composition of Hydroxylapatite for Surgical Implants	原採認標準
641.	8 Materials 材料	ASTM	ASTM F136	2021	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	原採認標準
642.	8 Materials 材料	ASTM	ASTM F2224	2020	Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants	原採認標準
643.	8 Materials 材料	ASTM	ASTM F2347	2024	Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications	原採認標準版本更新
644.	8 Materials 材料	ASTM	ASTM F2565	2021	Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Applications	
645.	8 Materials 材料	ASTM	ASTM F2695	2020	Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications	原採認標準
646.	8 Materials 材料	ASTM	ASTM F2820	2024	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	原採認標準版本更新
647.	8 Materials 材料	ASTM	ASTM F2971	2021	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing	原採認標準
648.	8 Materials 材料	ASTM	ASTM F3087	2015	Standard Specification for Acrylic Molding Resins for Medical Implant Applications	原採認標準
649.	8 Materials 材料	ISO	ISO 13356	2015	Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia (Y – TZP).	原採認標準
650.	8 Materials 材料	ISO	ISO 14708-1	2014	Implants for surgery — Active implantable medical devices —Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	原採認標準
651.	8 Materials 材料	ISO	ISO 5832-1	2024	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel	原採認標準
652.	8 Materials 材料	ISO	ISO 5832-11	2024	Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy	原採認標準
653.	8 Materials 材料	ISO	ISO 5832-3	2021	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	原採認標準
654.	8 Materials 材料	ISO	ISO 5832-4	2024	Implants for surgery - Metallic materials - Part 4:	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Cobalt-chromium-molybdenum casting alloy	
655.	8 Materials 材料	ISO	ISO 5832-7	2024	Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobaltchromium-nickel-molybdenum-iron alloy	原採認標準
656.	8 Materials 材料	ISO	ISO/ASTM 52900	2021	Standard Terminology for Additive Manufacturing – General Principles – Terminology	原採認標準
657.	8 Materials 材料	ISO	ISO/ASTM 52921	2013	Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies	原採認標準
658.	8 Materials 材料	ASTM	ASTM D412	2021	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension	原採認標準
659.	8 Materials 材料	ASTM	ASTM F1925	2024	Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants	原採認標準版本更新
660.	8 Materials 材料	ASTM	ASTM F2026	2023	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	原採認標準
661.	8 Materials 材料	ASTM	ASTM F2459	2024	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis	原採認標準版本更新
662.	8 Materials 材料	ISO	ISO 10974	2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	原採認標準
663.	8 Materials 材料	ASTM	ASTM F2052	2021	Standard Test Method for Measurement of	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	
664.	8 Materials 材料	ISO	ISO 5832-2	2018	Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium	原採認標準
665.	8 Materials 材料	ISO	ISO/ASTM 52901	2017	Additive manufacturing — General principles — Requirements for purchased AM parts	原採認標準
666.	8 Materials 材料	AAMI	AAMI ST65	2018	Processing of reusable surgical textiles for use in health care facilities	原採認標準
667.	8 Materials 材料	ASTM	ASTM F2393	2020	Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications	原採認標準
668.	8 Materials 材料	ASTM	ASTM F621	2021	Standard Specification for Stainless Steel Forgings for Surgical Implants	原採認標準
669.	8 Materials 材料	ASTM	ASTM F1581	2020	Standard Specification for Composition of Anorganic Bone for Surgical Implants	原採認標準
670.	8 Materials 材料	ASTM	ASTM F3260	2018	Standard Test Method for Determining the Flexural Stiffness of Medical Textiles	原採認標準
671.	8 Materials 材料	ISO	ISO 5834-3	2025	Implants for surgery — Ultra-high-molecular-weight polyethylene Part 3: Accelerated ageing methods after gamma irradiation in air	原採認標準版本更新
672.	8 Materials 材料	ISO	ISO 5834-4	2025	Implants for surgery — Ultra-high-molecular-weight polyethylene	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Part 4: Oxidation index measurement method	
673.	8 Materials 材料	ISO	ISO 5834-5	2025	Implants for surgery — Ultra-high-molecular-weight polyethylene Part 5: Morphology assessment method	原採認標準版本更新
674.	8 Materials 材料	ISO	ISO 5832-9	2019	Implants for surgery -- Metallic materials -- Part 9:Wrought high nitrogen stainless steel	原採認標準
675.	8 Materials 材料	ISO	ISO 5832-12	2019	Implants for surgery -- Metallic materials -- Part 12:Wrought cobalt-chromium-molybdenum alloy	原採認標準
676.	8 Materials 材料	ISO	ISO 5834-1	2025	Implants for surgery — Ultra-high-molecular-weight polyethylene Part 1: Powder form	原採認標準版本更新
677.	8 Materials 材料	ISO	ISO 6474-1	2019	Implants for surgery -- Ceramic materials -- Part 1:Ceramic materials based on high purity alumina	原採認標準
678.	8 Materials 材料	ISO	ISO 811	2018	Textiles - Determination of resistance to water penetration - Hydrostatic pressure test	原採認標準
679.	8 Materials 材料	ASTM	ASTM F2063	2018	Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	原採認標準
680.	8 Materials 材料	ISO	ISO 5834-2	2025	Implants for surgery — Ultra-high-molecular-weight polyethylene Part 2: Moulded forms	原採認標準版本更新
681.	8 Materials 材料	ASTM	ASTM F3268	2018	Standard Guide for in vitro Degradation Testing of Absorbable Metals	原採認標準
682.	8 Materials 材料	ISO	ISO/ASTM	2018	Additive manufacturing - Design - Requirements,	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

			52910		guidelines and recommendations	
683.	8 Materials 材料	ASTM	ASTM F2977	2020	Standard Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants	原採認標準
684.	8 Materials 材料	ASTM	ASTM F2313	2024	Standard Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide	原採認標準版本更新
685.	8 Materials 材料	ASTM	ASTM F3044	2020	Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants	原採認標準
686.	8 Materials 材料	ASTM	ASTM F629	2024	Standard Practice for Radiography of Cast Metallic Surgical Implants	原採認標準版本更新
687.	8 Materials 材料	ASTM	ASTM F961	2025	Standard Specification for 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)	原採認標準版本更新
688.	8 Materials 材料	ASTM	ASTM F3301	2018	Standard for Additive Manufacturing—Post Processing Methods—Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion.	原採認標準
689.	8 Materials 材料	ASTM	ASTM F3302	2018	Standard for Additive Manufacturing—Finished Part Properties—Standard Specification for Titanium Alloys via Powder Bed Fusion	原採認標準
690.	8 Materials 材料	ASTM ISO	ISO/ASTM 52904	2024	Standard for Additive Manufacturing—Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Applications.	
691.	8 Materials 材料	ISO	ISO 13782	2019	Implants for surgery -- Metallic materials -- Unalloyed tantalum for surgical implant applications	原採認標準
692.	8 Materials 材料	ISO	ISO 13938-1	2019	Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension	原採認標準
693.	8 Materials 材料	ASTM	ASTM F1091	2025	Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605)	原採認標準版本 更新
694.	8 Materials 材料	ASTM	ASTM F139	2019	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	原採認標準
695.	8 Materials 材料	ASTM	ASTM F1537	2020	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	原採認標準
696.	8 Materials 材料	ASTM	ASTM F2129	2025	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	原採認標準版本 更新
697.	8 Materials 材料	ASTM	ASTM F3208	2020	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices	原採認標準
698.	8 Materials 材料	ASTM	ASTM D638	2022	Standard Test Method for Tensile Properties of	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Plastics	
699.	8 Materials 材料	ASTM	ASTM E647	2024	Standard Test Method for Measurement of Fatigue Crack Growth Rates	原採認標準版本更新
700.	8 Materials 材料	ASTM	ASTM F2633	2019	Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants	原採認標準
701.	8 Materials 材料	ASTM	ASTM F3321	2019	Standard Guide for Methods of Extraction of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices	原採認標準
702.	8 Materials 材料	ASTM ISO	ISO/ASTM 52907	2019	Additive Manufacturing - Feedstock materials - Methods to characterize metal powders	原採認標準
703.	8 Materials 材料	ASTM ISO	ISO/ASTM 52911-1	2019	Additive Manufacturing - Design - Part 1: Laser-based powder bed fusion of metals	原採認標準
704.	8 Materials 材料	ASTM ISO	ISO/ASTM 52911-2	2019	Additive Manufacturing - Design - Part 2: Laser-based powder bed fusion of polymers	原採認標準
705.	8 Materials 材料	ASTM ISO	ISO/ASTM 52902	2023	Additive Manufacturing -Test Artifacts - Geometric capability assessment of additive manufacturing systems	原採認標準
706.	8 Materials 材料	ASTM	ASTM F3335	2020	Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion	原採認標準
707.	8 Materials 材料	ASTM ISO	ASTM ISO 52915	2020	Specification for additive manufacturing file format (AMF) Version 1.2	原採認標準
708.	8 Materials 材料	ASTM	ASTM F2181	2020	Standard Specification for Wrought Seamless	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Stainless Steel Tubing for Surgical Implants	
709.	8 Materials 材料	ASTM ISO	ASTM ISO TR 52912	2020	Additive manufacturing - Design - Functionally graded additive manufacturing	原採認標準
710.	8 Materials 材料	ASTM	ASTM F620	2020	Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition	原採認標準
711.	8 Materials 材料	ASTM	ASTM F3434	2021	Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment	原採認標準版本更新
712.	8 Materials 材料	ASTM	ASTM F2895	2024	Standard Practice for Digital Radiography of Cast Metallic Implants	原採認標準版本更新
713.	8 Materials 材料	ASTM ISO	ASTM ISO 52903-1	2020	Additive manufacturing - Material extrusion-based additive manufacturing of plastic materials - Part 1: Feedstock materials	原採認標準
714.	8 Materials 材料	ASTM	ASTM F1472	2023	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)	原採認標準
715.	8 Materials 材料	ASTM	ASTM F3333	2020	Standard Specification for Chopped Carbon Fiber Reinforced (CFR) Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	原採認標準
716.	8 Materials 材料	ASTM	ASTM F640	2023	Standard Test Methods for Determining Radiopacity for Medical Use	原採認標準
717.	8 Materials 材料	ASTM	ASTM F67	2024	Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					R50400, UNS R50550, UNS R50700)	
718.	8 Materials 材料	ASTM	ASTM F2754/F2754M	2021	Standard Test Method for Measurement of Camber, Cast, Helix and Direction of Helix of Coiled Wire	原採認標準
719.	8 Materials 材料	ASTM	ASTM F560	2022	Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	原採認標準
720.	8 Materials 材料	ASTM	ASTM F648	2021	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	原採認標準
721.	8 Materials 材料	ASTM	ASTM F1813	2021	Standard Specification for Wrought Titanium - 12 Molybdenum - 6 Zirconium - 2 Iron Alloy for Surgical Implant (UNS R58120)	原採認標準
722.	8 Materials 材料	ASTM	ASTM F1586	2021	Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)	原採認標準
723.	8 Materials 材料	ASTM	ASTM F3384	2021	Standard Specification for Polydioxanone Polymer Resins for Surgical Implants	原採認標準
724.	8 Materials 材料	ISO	ISO 13779-3	2021	Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity Amendment 1	原採認標準版本更新
725.	8 Materials 材料	IEC	IEC 63145-22-10	2020	Eyewear display -- Part 22-10: Specific measurement methods for AR type -- Optical properties	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

726.	8 Materials 材料	IEC	IEC 63145-20-10	2019	Eyewear display -- Part 20-10: Fundamental measurement methods -- Optical properties	原採認標準
727.	8 Materials 材料	IEC	IEC 63145-20-20	2019	Eyewear display -- Part 20-20: Fundamental measurement methods -- Image quality	原採認標準
728.	8 Materials 材料	ASTM	ASTM F1108	2021	Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)	原採認標準
729.	8 Materials 材料	ASTM	ASTM F1377	2021	Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for Medical Devices (UNS R30075, UNS R31537, and UNS R31538)	原採認標準
730.	8 Materials 材料	ASTM	ASTM F2989	2021	Standard Specification for Metal Injection Molded Unalloyed Titanium Components for Surgical Implant Applications	原採認標準
731.	8 Materials 材料	ASTM	ASTM F1801	2020	Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials	原採認標準
732.	8 Materials 材料	ASTM	ASTM F2005	2021	Standard Terminology for Nickel-Titanium Shape Memory Alloys	原採認標準
733.	8 Materials 材料	ASTM	ASTM F2146	2022	Standard Specification for Wrought Titanium-3Aluminum-2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320)	原採認標準
734.	8 Materials 材料	ASTM	ASTM F2229	2021	Standard Specification for Wrought, Nitrogen Strengthened	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108)	
735.	8 Materials 材料	ISO	ISO 13779-6	2016	Implants for surgery - Hydroxyapatite - Part 6: Powders	原採認標準
736.	8 Materials 材料	ISO	ISO 13179-1	2021	Implants for surgery -- Coatings on metallic surgical implants -- Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders	原採認標準
737.	8 Materials 材料	ASTM	ASTM F2848	2021	Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns	原採認標準
738.	8 Materials 材料	ASTM	ASTM F3160	2021	Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants	原採認標準
739.	8 Materials 材料	ASTM	ASTM F2458	2015	Standard Test Method For Wound Closure Strength Of Tissue Adhesives And Sealants	原採認標準
740.	8 Materials 材料	ASTM	ASTM F2258	2024	Standard Test Method For Strength Properties Of Tissue Adhesives In Tension	原採認標準版本 更新
741.	8 Materials 材料	ASTM	ASTM F2256	2024	Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	原採認標準版本 更新
742.	8 Materials 材料	ASTM	ASTM F2255	2024	Standard Test Method For Strength Properties Of Tissue Adhesives In Lap-Shear By Tension Loading	原採認標準版本 更新
743.	8 Materials 材料	ASTM	ASTM D3654/D3654 M	2019	Standard Test Methods For Shear Adhesion Of Pressure-Sensitive Tapes	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

744.	8 Materials 材料	ASTM	ASTM D3330/D3330 M	2018	Standard Test Method For Peel Adhesion Of Pressure-Sensitive Tape	原採認標準
745.	8 Materials 材料	ASTM	ASTM F2003	2022	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air	原採認標準
746.	8 Materials 材料	ASTM	ASTM F2516	2022	Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials	原採認標準
747.	8 Materials 材料	ASTM	ASTM F1295	2024	Standard Specification for Wrought Titanium-6 Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)	原採認標準版本更新
748.	8 Materials 材料	ASTM	ASTM F3109	2023	Standard Test Method for Verification of Multi-Axis Force Measuring Platforms	原採認標準版本更新
749.	8 Materials 材料	ASTM	ASTM F2257	2022	Standard Specification for Wrought Seamless or Welded and Drawn 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673)	原採認標準
750.	8 Materials 材料	ISO	ISO 9584	2023	Implants for surgery - Non-destructive testing - Radiographic examination of cast metallic surgical implants	原採認標準
751.	8 Materials 材料	ASTM	ASTM F2527	2024	Standard Specification for Wrought Seamless and Welded and Drawn Cobalt Alloy Small Diameter Tubing for Surgical Implants	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

752.	8 Materials 材料	ASTM	ASTM F3456	2022	Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials	原採認標準
753.	8 Materials 材料	ISO ASTM	ISO ASTM 52926-1	2023	Additive manufacturing of metals - Qualification principles - Part 1: General qualification of operators	原採認標準
754.	8 Materials 材料	ISO ASTM	ISO ASTM 52926-2	2023	Additive manufacturing of metals - Qualification principles - Part 2: Qualification of operators for PBF-LB	原採認標準
755.	8 Materials 材料	ISO ASTM	ISO ASTM 52926-3	2023	Additive manufacturing of metals - Qualification principles - Part 3: Qualification of operators for PBF-EB	原採認標準
756.	8 Materials 材料	ASTM	ASTM F1609	2023	Standard Specification for Calcium Phosphate Coatings for Implantable Materials	原採認標準
757.	8 Materials 材料	ASTM	ASTM F2537	2023	Standard Practice for Calibration of Linear Displacement Sensor Systems Used to Measure Micromotion	原採認標準
758.	8 Materials 材料	ASTM	ASTM F2214	2023	Standard Test Method for In Situ Determination of Network Parameters of Crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE)	原採認標準
759.	8 Materials 材料	ASTM	ASTM F601	2023	Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	原採認標準
760.	8 Materials 材料	ASTM	ASTM F1350	2024	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)	115 年度新增採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

761.	8 Materials 材料	ASTM	ASTM F1314	2024	Standard Specification for Wrought Nitrogen Strengthened 22Chromium-13Nickel-5Manganese-2.5Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)	115 年度新增採認標準
762.	8 Materials 材料	ASTM	ASTM E2948	2024	Standard Test Method for Conducting Rotating Bending Fatigue Tests of Solid Round Fine Wire	115 年度新增採認標準
763.	8 Materials 材料	ASTM	ASTM F3604	2023	Standard Practice for Validating the Additive Manufacturing (AM) Production Process for Medical Devices Produced Using Laser Powder Bed Fusion.	115 年度新增採認標準
764.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	CIE ISO	ISO/CIE 11664-2	2022	Colorimetry - Part 2: CIE standard illuminants	原採認標準
765.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	CIE ISO	ISO/CIE 11664-6	2022	Colorimetry - Part 6: CIEDE2000 colour-difference formula	原採認標準
766.	9 ObGyn/Gastroenterology 胃腸病科學及泌尿科學/婦產科學	IEC	IEC 60601-2-18	2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	原採認標準
767.	9 ObGyn/Gastroenterology	CNS	CNS 14194	1998	血液透析器、血液過濾器、血液濃縮器之體外迴路管 (Extracorporeal blood circuit for haemodialysers)	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	y 胃腸病科學及泌尿科學/婦產科學				hasmofilters and haemoconcentrators)	
768.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	CNS	CNS 6629	2024	天然乳膠男性衛生套—要求及試驗法 (Natural rubber latex male condoms - Requirements and test methods)	原採認標準版本更新
769.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ASTM	ASTM D1894	2024	Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheet	原採認標準版本更新
770.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 4074	2015	Natural latex rubber condoms - Requirements and test methods	原採認標準
771.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 7439	2023	Copper-bearing contraceptive intrauterine devices — Requirements and tests	原採認標準
772.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8009	2014	Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests	原採認標準
773.	9 ObGyn/Gastroenterolog	ISO	ISO 8637-1	2024	Extracorporeal systems for blood purification -- Part 1: Haemodialysers, haemodiafilters, haemofilters and	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	y 胃腸病科學及泌尿科學/婦產科學				haemoconcentrators	
774.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ASTM	ASTM F1828	2022	Standard Specification for Ureteral Stents	原採認標準
775.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	IEC	IEC 60601-2-16	2025	Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	原採認標準版本更新
776.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 29943-1	2017	Condoms—Guidance on clinical studies—Part 1: Male condoms, clinical function studies based on self-reports	原採認標準
777.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 29943-2	2017	Condoms — Guidance on clinical studies Part 2: Female condoms, clinical function studies based on self-reports	原採認標準
778.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8637-2	2024	Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters	原採認標準
779.	9 ObGyn/Gastroenterology	AAMI	AAMI/ISO 23500-1	2019	Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	y 胃腸病科學及泌尿科學/婦產科學				requirements	
780.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	EN	ISO 20695	2020	Enteral feeding systems — Design and testing	原採認標準
781.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	AAMI	AAMI RD47	2020	Reprocessing of hemodialyzers	原採認標準
782.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	CIE ISO	ISO/CIE 11664-1	2019	Colorimetry - Part 1: CIE standard colorimetric observers	原採認標準
783.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-3	2024	Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies	原採認標準
784.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-2	2024	Preparation and quality management of fluids for haemodialysis and related therapies Part 2: Water treatment equipment for haemodialysis applications and related therapies	原採認標準版本更新
785.	9 ObGyn/Gastroenterolog	CIE ISO	ISO/CIE 11664-3	2019	Colorimetry - Part 3: CIE tristimulus values	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	y 胃腸病科學及泌尿科學/婦產科學					
786.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	CIE ISO	ISO/CIE 11664-4	2019	Colorimetry - Part 4: CIE 1976 L*a*b* colour space	原採認標準
787.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	CIE ISO	CIE ISO 11664-5	2024	Colorimetry - Part 5: CIE 1976 L*u*v* colour space and u',v' uniform chromaticity scale diagram	原採認標準
788.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-5	2024	Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies	原採認標準
789.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 23500-4	2024	Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies	原採認標準
790.	9 ObGyn/Gastroenterolog y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8600-3	2019	Endoscopes — Medical endoscopes and endotherapy devices —Part 3: Determination of field of view and direction of view of endoscopes with optics	原採認標準
791.	9 ObGyn/Gastroenterolog	ISO	ISO 8600-5	2020	Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	y 胃腸病科學及泌尿科學/婦產科學				optical resolution of rigid endoscopes with optics	
792.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	IEC	IEC 60601-2-39	2024	Medical electrical equipment - Part 2-39: Particular requirements for the basic safety and essential performance of peritoneal dialysis equipment	原採認標準版本更新
793.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 20696	2018	Sterile urethral catheters for single use	原採認標準
794.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ASTM	ASTM D7661	2023	Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms	原採認標準版本更新
795.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 20697	2018	Sterile drainage catheters and accessory devices for single use	原採認標準
796.	9 ObGyn/Gastroenterology y 胃腸病科學及泌尿科學/婦產科學	ISO	ISO 8600-4	2023	Endoscopes - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion	原採認標準
797.	9 ObGyn/Gastroenterology	JSA	JIS T 3245	2011	Tubes and catheters designed for gamete or embryo transfers	115 年度新增採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	y 胃腸病科學及泌尿科學/婦產科學					
798.	10 Ophthalmic 眼科學	ISO	ISO 18369-1	2017	Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications	原採認標準
799.	10 Ophthalmic 眼科學	ISO	ISO 18369-2	2017	Ophthalmic optics - Contact lenses - Part 2: Tolerances	原採認標準
800.	10 Ophthalmic 眼科學	ISO	ISO 18369-3	2017	Ophthalmic optics - Contact lenses - Part 3: Measurement methods	原採認標準
801.	10 Ophthalmic 眼科學	ISO	ISO 18369-4	2017	Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials	原採認標準
802.	10 Ophthalmic 眼科學	CNS	CNS 12446	1988	軟性隱形眼鏡片	原採認標準
803.	10 Ophthalmic 眼科學	ISO	ISO 8980-4	2006	Ophthalmic optics -- Uncut finished spectacle lenses -- Part 4: Specifications and test methods for anti-reflective coatings	原採認標準
804.	10 Ophthalmic 眼科學	ISO	ISO 8980-5	2005	Ophthalmic optics -- Uncut finished spectacle lenses -- Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant	原採認標準
805.	10 Ophthalmic 眼科學	CNS	CNS 15448-1	2011	眼科光學－未切邊之眼鏡鏡片成品－第 1 部：單光與多焦點眼鏡鏡片規格 (Ophthalmic optics - Uncut finished spectacle lenses - Part 1: Specifications for single-vision and multifocal lenses)(IDT: ISO 8980-1:2004)	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

806.	10 Ophthalmic 學	眼科	CNS	CNS 15448-2	2011	眼科光學－未切邊之眼鏡鏡片成品－第 2 部：漸進多焦點眼鏡鏡片規格 (Ophthalmic optics - Uncut finished spectacle lenses - Part 2: Specifications for progressive lenses) (IDT: ISO 8980-2:2004)	原採認標準
807.	10 Ophthalmic 學	眼科	ISO	ISO 10936-2	2010	Optics and photonics -- Operation microscopes -- Part 2: Light hazard from operation microscopes used in ocular surgery	原採認標準
808.	10 Ophthalmic 學	眼科	ISO	ISO 11979-3	2012	Ophthalmic Implants - Intraocular Lenses - Part 3: Mechanical Properties and Test Methods	原採認標準
809.	10 Ophthalmic 學	眼科	ISO	ISO 11979-5	2020	Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility	原採認標準
810.	10 Ophthalmic 學	眼科	ISO	ISO 11987	2012	Ophthalmic optics -- Contact lenses -- Determination of shelf-life	原採認標準
811.	10 Ophthalmic 學	眼科	ISO	ISO 14534	2011	Ophthalmic optics -- Contact lenses and contact lens care products -- Fundamental requirements	原採認標準
812.	10 Ophthalmic 學	眼科	ISO	ISO 8980-3	2022	Ophthalmic optics -- Uncut finished spectacle lenses -- Part 3: Transmittance specifications and test methods	原採認標準
813.	10 Ophthalmic 學	眼科	ISO	ISO 9394	2012	Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of biocompatibility by ocular study with rabbit eyes	原採認標準
814.	10 Ophthalmic 學	眼科	ANSI	ANSI Z80.7	2023	Ophthalmic Optics - Intraocular Lenses	原採認標準
815.	10 Ophthalmic 學	眼科	ISO	ISO 18189	2016	Ophthalmic optics — Contact lenses and contact	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	學					lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/ solution interactions	
816.	10 Ophthalmic 眼科學	ANSI	ANSI Z80.36	2021		Ophthalmic - Light Hazard Protection for Ophthalmic Instruments	原採認標準
817.	10 Ophthalmic 眼科學	ISO	ISO 11979-2	2024		Ophthalmic implants — Intraocular lenses Part 2: Optical properties and test methods	原採認標準版本更新
818.	10 Ophthalmic 眼科學	ISO	ISO 14730	2014		Ophthalmic optics -- Contact lens care products -- Antimicrobial preservative efficacy testing and guidance on determining discard date	原採認標準
819.	10 Ophthalmic 眼科學	IEC	IEC 80601-2-58	2024		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	原採認標準版本更新
820.	10 Ophthalmic 眼科學	ISO	ISO 10936-1	2017		Optics and photonics - Operation microscopes - Part 1: Requirements and test methods	原採認標準
821.	10 Ophthalmic 眼科學	ISO	ISO 11979-8	2017		Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements	原採認標準
822.	10 Ophthalmic 眼科學	ISO	ISO 11986	2017		Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release	原採認標準
823.	10 Ophthalmic 眼科學	ISO	ISO 15798	2022		Ophthalmic implants — Ophthalmic viscosurgical devices	原採認標準版本更新
824.	10 Ophthalmic 眼科學	ISO	ISO 11979-10	2018		Ophthalmic implants - Intraocular lenses - Part 10:	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	學				Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes	
825.	10 Ophthalmic 眼科 學	ISO	ISO 11981	2017	Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses	原採認標準
826.	10 Ophthalmic 眼科 學	ISO	ISO 8980-1	2017	Ophthalmic optics - Uncut finished spectacle lenses - Part 1: Specifications for single-vision and multifocal lenses	原採認標準
827.	10 Ophthalmic 眼科 學	ISO	ISO 8980-2	2017	Ophthalmic optics - Uncut finished spectacle lenses - Part 2: Specifications for power-variation lenses	原採認標準
828.	10 Ophthalmic 眼科 學	ISO	ISO 11979-7	2024	Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia	原採認標準
829.	10 Ophthalmic 眼科 學	ISO	ISO 11979-1	2018	Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary	原採認標準
830.	10 Ophthalmic 眼科 學	ASTM	ASTM D882	2018	Standard Test Method for Tensile Properties of Thin Plastic Sheeting	原採認標準
831.	10 Ophthalmic 眼科 學	ISO	ISO 15004-2	2024	Ophthalmic instruments — Fundamental requirements and test methods Part 2: Light hazard protection	原採認標準版本更新
832.	10 Ophthalmic 眼科 學	ISO	ISO 15004-1	2020	Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

833.	10 Ophthalmic 眼科學	ANSI	ANSI Z80.20	2021	Contact Lenses - Standard Terminology, Tolerances Measurements and Physiochemical Properties	原採認標準
834.	10 Ophthalmic 眼科學	ISO	ISO 16672	2020	Ophthalmic implants - Ocular endotamponades	原採認標準
835.	10 Ophthalmic 眼科學	ISO	ISO TR 22979	2017	Ophthalmic implants - Intraocular Lenses - Guidance on assessment of the need for clinical investigation of intraocular lens design modifications	原採認標準
836.	10 Ophthalmic 眼科學	ISO	ISO 10942	2022	Ophthalmic instruments - Direct ophthalmoscopes	原採認標準
837.	10 Ophthalmic 眼科學	ISO	ISO 10943	2023	Ophthalmic instruments - Indirect ophthalmoscopes	原採認標準
838.	10 Ophthalmic 眼科學	ISO	ISO 16971-1	2024	Ophthalmic instruments - Optical coherence tomographs - Part 1: Optical coherence tomographs for the posterior segment of the human eye	115 年度新增採認標準
839.	10 Ophthalmic 眼科學	ANSI	ANSI Z80.10	2018	Ophthalmics - Ophthalmic Instruments - Tonometers	115 年度新增採認標準
840.	11 Orthopaedics 骨科學	ASTM	ASTM F2665	2021	Standard Specification for Total Ankle Replacement Prosthesis	原採認標準
841.	11 Orthopaedics 骨科學	ISO	ISO 5838-2	1991	Implants for surgery -- Skeletal pins and wires -- Part 2: Steinmann skeletal pins -- Dimensions	原採認標準
842.	11 Orthopaedics 骨科學	ISO	ISO 5838-3	1993	Implants for surgery -- Skeletal pins and wires -- Part 3: Kirschner skeletal wires	原採認標準
843.	11 Orthopaedics 骨科學	ISO	ISO 7207-1	2007	Implants for surgery -- Components for partial and total knee joint prostheses -- Part 1: Classification,	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					definitions and designation of dimensions	
844.	11 Orthopaedics 骨科學	ISO	ISO 14243-1	2020	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	原採認標準
845.	11 Orthopaedics 骨科學	ISO	ISO 14602	2010	Non-active surgical implants -- Implants for osteosynthesis -- Particular requirements	原採認標準
846.	11 Orthopaedics 骨科學	ISO	ISO 14630	2024	Non-active surgical implants — General requirements	原採認標準版本更新
847.	11 Orthopaedics 骨科學	ISO	ISO 5833	2002	Implants for Surgery - Acrylic Resin Cements	原採認標準
848.	11 Orthopaedics 骨科學	ISO	ISO 5838-1	2013	Implants for surgery -- Metallic skeletal pins and wires -- Part 1: General requirements	原採認標準
849.	11 Orthopaedics 骨科學	ASTM	ASTM F2996	2024	Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems	原採認標準版本更新
850.	11 Orthopaedics 骨科學	ASTM	ASTM D2990	2017	Standard Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics	原採認標準
851.	11 Orthopaedics 骨科學	ASTM	ASTM D790	2017	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	原採認標準
852.	11 Orthopaedics 骨科學	ASTM	ASTM F116	2021	Standard Specification for Medical Screwdriver Bits	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

853.	11 Orthopaedics 骨科學	ASTM	ASTM F2091	2015	Standard Specification for Acetabular Prostheses	原採認標準
854.	11 Orthopaedics 骨科學	ASTM	ASTM F2180	2024	Standard Specification for Metallic Implantable Strands and Cables	原採認標準版本更新
855.	11 Orthopaedics 骨科學	ASTM	ASTM F2582	2020	Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components	原採認標準
856.	11 Orthopaedics 骨科學	ASTM	ASTM F2887	2023	Standard Specification for Total Elbow Prostheses	原採認標準
857.	11 Orthopaedics 骨科學	ASTM	ASTM F2979	2020	Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses	原採認標準
858.	11 Orthopaedics 骨科學	ASTM	ASTM F3161	2024	Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions	原採認標準版本更新
859.	11 Orthopaedics 骨科學	ASTM	ASTM F451	2021	Standard Specification for Acrylic Bone Cement	原採認標準
860.	11 Orthopaedics 骨科學	ISO	ISO 14242-2	2016	Implants for surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement	原採認標準
861.	11 Orthopaedics 骨科學	ISO	ISO 14243-2	2016	Implants for surgery - Wear of total knee-joint prostheses - Part 2: Methods of measurement	原採認標準
862.	11 Orthopaedics 骨科學	ISO	ISO 21535	2023	Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants	原採認標準
863.	11 Orthopaedics 骨科學	ISO	ISO 21536	2023	Non-active surgical implants — Joint replacement	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	學				implants — Specific requirements for knee-joint replacement implants	
864.	11 Orthopaedics 骨科學	ISO	ISO 7207-2	2025	Implants for surgery — Components for partial and total knee joint prostheses Part 2: Articulating surfaces made of metal, ceramic and plastics materials	原採認標準版本更新
865.	11 Orthopaedics 骨科學	ASTM	ASTM D732	2024	Standard Test Method for Shear Strength of Plastics by Punch Tool	原採認標準版本更新
866.	11 Orthopaedics 骨科學	ASTM	ASTM F1541	2024	Standard Specification and Test Methods for External Skeletal Fixation Devices	原採認標準版本更新
867.	11 Orthopaedics 骨科學	ASTM	ASTM F1829	2023	Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear	原採認標準
868.	11 Orthopaedics 骨科學	ASTM	ASTM F1978	2022	Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser	原採認標準
869.	11 Orthopaedics 骨科學	ASTM	ASTM F2028	2017	Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation	原採認標準
870.	11 Orthopaedics 骨科學	ASTM	ASTM F2502	2024	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants	原採認標準版本更新
871.	11 Orthopaedics 骨科學	ISO	ISO 13175-3	2012	Implants for surgery - Calcium phosphates - Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes	原採認標準
872.	11 Orthopaedics 骨科學	ASTM	ASTM F2267	2024	Standard Test Method for Measuring Load Induced	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	學				Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression	
873.	11 Orthopaedics 骨科學	ASTM	ASTM F1714	2018	Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices.	原採認標準
874.	11 Orthopaedics 骨科學	ASTM	ASTM F2423	2020	Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses	原採認標準
875.	11 Orthopaedics 骨科學	ASTM	ASTM F2624	2020	Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs	原採認標準
876.	11 Orthopaedics 骨科學	ASTM	ASTM F1378	2018	Standard Specification for Shoulder Prostheses	原採認標準
877.	11 Orthopaedics 骨科學	ASTM	ASTM F1717	2021	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	原採認標準版本更新
878.	11 Orthopaedics 骨科學	ASTM	ASTM F2077	2024	Test Methods For Intervertebral Body Fusion Devices	原採認標準版本更新
879.	11 Orthopaedics 骨科學	ASTM	ASTM F2554	2022	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems	原採認標準
880.	11 Orthopaedics 骨科學	ISO	ISO 14242-3	2019	Implants for surgery — Wear of total hipjoint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test	原採認標準
881.	11 Orthopaedics 骨科學	ASTM	ASTM F2580	2024	Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Prosthesis	
882.	11 Orthopaedics 骨科學	ASTM	ASTM F2193	2020	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	原採認標準
883.	11 Orthopaedics 骨科學	ISO	ISO 14242-1	2018	Implants for surgery — Wear of total hipjoint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test	原採認標準
884.	11 Orthopaedics 骨科學	ISO	ISO 19227	2018	Implants for surgery - Cleanliness of orthopedic implants - General requirements	原採認標準
885.	11 Orthopaedics 骨科學	ASTM	ASTM F2789	2020	Standard Guide for Mechanical and Functional Characterization of Nucleus Devices	原採認標準
886.	11 Orthopaedics 骨科學	ASTM	ASTM F2009	2020	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses	原採認標準
887.	11 Orthopaedics 骨科學	ASTM	ASTM F2381	2019	Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy	原採認標準
888.	11 Orthopaedics 骨科學	ASTM	ASTM F2943	2025	Standard Guide for Presentation of End User Labeling Information for Musculoskeletal Implants	原採認標準版本更新
889.	11 Orthopaedics 骨科學	ASTM	ASTM F1357	2023	Standard Specification for Articulating Total Wrist Implants	原採認標準
890.	11 Orthopaedics 骨科學	ASTM	ASTM F1611	2020	Standard Specification for Intramedullary Reamers	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	學					
891.	11 Orthopaedics 骨科學	ASTM	ASTM F2385	2019	Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs	原採認標準
892.	11 Orthopaedics 骨科學	ASTM	ASTM E399	2024	Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Metallic Materials	原採認標準版本更新
893.	11 Orthopaedics 骨科學	ISO	ISO 15142-2	2003	Implants for surgery - Metal intramedullary nailing systems - Part 2: Locking components	原採認標準
894.	11 Orthopaedics 骨科學	ISO	ISO 15142-1	2003	Implants for surgery — Metal intramedullary nailing systems — Part 1: Intramedullary nails	原採認標準
895.	11 Orthopaedics 骨科學	ASTM	ASTM F1264	2024	Standard Specification and Test Methods for Intramedullary Fixation Devices	原採認標準版本更新
896.	11 Orthopaedics 骨科學	ASTM	ASTM F543	2023	Standard Specification and Test Methods for Metallic Medical Bone Screws	原採認標準版本更新
897.	11 Orthopaedics 骨科學	ASTM	ASTM F897	2019	Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	原採認標準
898.	11 Orthopaedics 骨科學	ISO	ISO 14243-3	2020	Implants for surgery - Wear of total knee-joint prostheses - Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	原採認標準
899.	11 Orthopaedics 骨科學	ASTM	ASTM F1800	2019	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

900.	11 Orthopaedics 骨科學	ASTM	ASTM F3334	2019	Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components	原採認標準
901.	11 Orthopaedics 骨科學	ASTM	ASTM F3292	2025	Standard Practice for Inspection of Spinal Implants Undergoing Testing	原採認標準版本更新
902.	11 Orthopaedics 骨科學	ASTM	ASTM F382	2024	Standard Specification and Test Method for Metallic Bone Plates	原採認標準版本更新
903.	11 Orthopaedics 骨科學	ASTM	ASTM F564	2024	Standard specification and test methods for metallic bone staples	原採認標準
904.	11 Orthopaedics 骨科學	ASTM	ASTM F3143	2020	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings under Standard Conditions Using a Reciprocal Friction Simulator	原採認標準
905.	11 Orthopaedics 骨科學	ASTM	ASTM F3446	2020	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator	原採認標準
906.	11 Orthopaedics 骨科學	ASTM	ASTM F1223	2020	Standard Test Method for Determination of Total Knee Replacement Constraint	原採認標準
907.	11 Orthopaedics 骨科學	ISO	ISO 14879-1	2020	Implants for surgery - Total knee-joint prostheses - Part 1: Determination of endurance properties of knee tibial trays	原採認標準
908.	11 Orthopaedics 骨科學	ASTM	ASTM F3090	2024	Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement and Performance Requirements	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

909.	11 Orthopaedics 骨科學	ASTM	ASTM F2033	2025	Standard Specification for Hip Joint Replacement Bearing Surfaces	原採認標準版本更新
910.	11 Orthopaedics 骨科學	ASTM	ASTM F2723	2021	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation	原採認標準
911.	11 Orthopaedics 骨科學	ASTM	ASTM F1820	2022	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices	原採認標準
912.	11 Orthopaedics 骨科學	ASTM	ASTM F3210	2022	Standard Test Method for Fatigue Testing of Total Knee Femoral Components Under Closing Conditions	原採認標準
913.	11 Orthopaedics 骨科學	ASTM	ASTM F3574	2022	Standard Test Methods for Sacroiliac Joint Fusion Devices	原採認標準
914.	11 Orthopaedics 骨科學	ASTM	ASTM F1814	2022	Standard Guide for Evaluating Modular Hip and Knee Joint Components	原採認標準
915.	11 Orthopaedics 骨科學	ISO	ISO 7206-13	2022	Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components Amendment 1	原採認標準版本更新
916.	11 Orthopaedics 骨科學	ASTM	ASTM F1798	2024	Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	原採認標準版本更新
917.	11 Orthopaedics 骨科學	ASTM	ASTM F3047M	2023	Standard Guide for High Demand Hip Simulator	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	學				Wear Testing of Hard-on-Hard Articulations	
918.	11 Orthopaedics 骨科 學	ASTM	ASTM F3141	2023	Standard Guide for Total Knee Replacement Loading Profiles	原採認標準
919.	11 Orthopaedics 骨科 學	ASTM	ASTM F3140	2023	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements	原採認標準
920.	11 Orthopaedics 骨科 學	ASTM	ASTM F2777	2023	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion	原採認標準
921.	11 Orthopaedics 骨科 學	ASTM	ASTM F3495	2023	Standard Test Methods for Determining the Static Failure Load of Ceramic Knee Femoral Components	原採認標準
922.	11 Orthopaedics 骨科 學	ASTM	ASTM F3129	2024	Standard Guide for Characterization of Material Loss from Conical Taper Junctions in Total Joint Prostheses	115 年度新增採認標準
923.	11 Orthopaedics 骨科 學	ASTM	ASTM F3631	2024	Standard Test Method for Assessment of Intra-operative Durability of Intervertebral Body Fusion Devices	115 年度新增採認標準
924.	11 Orthopaedics 骨科 學	ASTM	ASTM F3690	2024	Standard Test Method for Evaluating Suture Anchor Insertion and Pull Displacement Resistance	115 年度新增採認標準
925.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-5	2008	Wheelchairs -- Part 5: Determination of dimensions, mass and manoeuvring space	原採認標準
926.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-9	2009	Wheelchairs -- Part 9: Climatic tests for electric wheelchairs	原採認標準
927.	12 Physical Medicine	ISO	ISO 7176-10	2008	Wheelchairs -- Part 10: Determination of	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物理醫學科學				obstacle-climbing ability of electrically powered wheelchairs	
928.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-6	2018	Wheelchairs Part 6: Determination of maximum speed of electrically powered wheelchairs	原採認標準
929.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-7	1998	Wheelchairs -- Part 7: Measurement of seating and wheel dimensions	原採認標準
930.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-13	1989	Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces	原採認標準
931.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-15	1996	Wheelchairs - Part 15: Requirements for Information Disclosure, Documentation and Labelling	原採認標準
932.	12 Physical Medicine 物理醫學科學	CNS	CNS 15037-1	2006	雙臂操作步行輔具－要求及測試法－第 1 部：助行器	原採認標準
933.	12 Physical Medicine 物理醫學科學	CNS	CNS 15037-2	2006	雙臂操作步行輔具－要求及測試法－第 2 部：帶輪助行器	原採認標準
934.	12 Physical Medicine 物理醫學科學	CNS	CNS 15037-3	2006	雙臂操作步行輔具－要求及測試法－第 3 部：附前臂支撐桌助行器	原採認標準
935.	12 Physical Medicine 物理醫學科學	CNS	CNS 15024-4	2006	單臂操作之步行輔具－要求與測試方法－第 4 部：三腳或多腳步行手杖	原採認標準
936.	12 Physical Medicine 物理醫學科學	CNS	CNS 14103-1	2009	義肢學與矯具學－詞彙－第 1 部：外用義肢與外用矯具之一般術語	原採認標準
937.	12 Physical Medicine 物理醫學科學	CNS	CNS 14103-2	2009	義肢學與矯具學－詞彙－第 2 部：外用義肢與其穿戴者之術語	原採認標準
938.	12 Physical Medicine	CNS	CNS 14103-3	2009	義肢學與矯具學－詞彙－第 3 部：外用矯具之術	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物理醫學科學				語	
939.	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-1	2009	義肢學與矯具學—肢體缺陷—第 1 部：先天性肢體缺陷之描述	原採認標準
940.	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-2	2009	義肢學與矯具學—肢體缺陷—第 2 部：下肢截肢之描述	原採認標準
941.	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-3	2009	義肢學與矯具學—肢體缺陷—第 3 部：上肢截肢之描述	原採認標準
942.	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-4	2009	義肢學與矯具學—肢體缺陷—第 4 部：導致截肢原因之描述	原採認標準
943.	12 Physical Medicine 物理醫學科學	CNS	CNS 14104-5	2009	義肢學與矯具學—肢體缺陷—第 5 部：截肢病患臨床狀態之描述	原採認標準
944.	12 Physical Medicine 物理醫學科學	CNS	CNS 15265-1	2009	義肢學與矯具學—義肢組件之分類與描述—第 1 部：義肢組件之分類	原採認標準
945.	12 Physical Medicine 物理醫學科學	CNS	CNS 15265-2	2009	義肢學與矯具學—義肢組件之分類與描述—第 2 部：下肢義肢組件之描述	原採認標準
946.	12 Physical Medicine 物理醫學科學	CNS	CNS 15265-3	2009	義肢學與矯具學—義肢組件之分類與描述—第 3 部：上肢義肢組件之描述	原採認標準
947.	12 Physical Medicine 物理醫學科學	CNS	CNS 15266	2009	義肢學—腕關節結構之測試方法	原採認標準
948.	12 Physical Medicine 物理醫學科學	CNS	CNS 15268	2009	外用義肢與外用矯具—要求與測試方法	原採認標準
949.	12 Physical Medicine 物理醫學科學	CNS	CNS 15269	2009	義肢學—下肢義肢結構測試—要求與測試方法	原採認標準
950.	12 Physical Medicine	CNS	CNS 14964	2020	輪椅—應用指導綱要	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物理醫學科學					更新
951.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-1	2017	輪椅－第 1 部：靜態穩定性之測定	原採認標準
952.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-2	2020	輪椅－第 2 部：電動輪椅動態穩定性之測定	原採認標準版本更新
953.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-4	2017	輪椅－第 4 部：電動輪椅及代步車之耗能－理論行駛距離之測定	原採認標準
954.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-6	2020	輪椅－第 6 部：電動輪椅最大速率之測定	原採認標準版本更新
955.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-7	2006	輪椅－第 7 部：座椅及輪子尺度之量測	原採認標準
956.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-8	2018	輪椅－第 8 部：輪椅靜力、衝擊與疲勞強度測試方法與要求	原採認標準
957.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-10	2017	輪椅－第 10 部：電動輪椅越障能力試驗	原採認標準
958.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-13	2006	輪椅－第 13 部：測試表面摩擦係數之測定	原採認標準
959.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-14	2005	輪椅－第 14 部：電動輪椅之電力與控制系統測試方法與要求	原採認標準
960.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-15	2007	輪椅－第 15 部：資訊宣告、文件與標示之要求	原採認標準
961.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-19	2023	輪椅－第 19 部：機動車輛使用之輪型移動裝置	原採認標準
962.	12 Physical Medicine	CNS	CNS 14964-21	2019	輪椅－第 21 部：電動輪椅及電動代步車之電磁相	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物理醫學科學				容性要求和測試方法	
963.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-22	2020	輪椅－第 22 部：設定程序	原採認標準
964.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-4	2008	Wheelchairs -- Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range	原採認標準
965.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-14	2025	Wheelchairs — Part 14: Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods Amendment 1: Correction of referred standard	原採認標準版本更新
966.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-21	2025	Wheelchairs Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	原採認標準版本更新
967.	12 Physical Medicine 物理醫學科學	CNS	CNS 15469-1	2011	步行輔具杖端－要求與試驗方法－第 1 部：杖端摩擦力 (Tips for assistive products for walking - Requirements and test methods - Part 1: Friction of tips) (IDT: ISO 24415-1:2009)	原採認標準
968.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-11	2012	Wheelchairs -- Part 11: Test dummies	原採認標準
969.	12 Physical Medicine 物理醫學科學	ISO	ISO 16840-10	2024	Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method Amendment 1: Amended with additional Annexes	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					and test method	
970.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-3	2012	Wheelchairs -- Part 3: Determination of effectiveness of brakes	原採認標準
971.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-16	2014	輪椅－第 16 部：姿勢支撐裝置之耐燃性 (Wheelchairs – Part 16: Resistance to ignition of postural support devices)	原採認標準
972.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-25	2014	輪椅－第 25 部：電動輪椅之電池組及充電器 (Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs)	原採認標準
973.	12 Physical Medicine 物理醫學科學	CNS	CNS 15469-2	2013	步行輔具杖端－要求與試驗方法－第 2 部：拐杖杖端耐用性 Tips for assistive products for walking – Requirements and test methods – Part 2: Durability of tips for crutches (IDT: ISO 24415-2:2011)	原採認標準
974.	12 Physical Medicine 物理醫學科學	CNS	CNS 15677-1	2013	失能者或生理障礙者之技術系統和輔具－輪椅束縛裝置和乘坐者安全拘束系統－第 1 部：全部系統之要求及測試方法 (Technical systems and aids for disabled or handicapped persons – Wheelchair tiedown and occupant-restraint systems – Part 1: Requirements and test methods for all systems)	原採認標準
975.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-3	2015	輪椅－第 3 部：煞車有效性之測定	原採認標準
976.	12 Physical Medicine	CNS	CNS 14964-5	2017	輪椅－第 5 部：尺度、質量及操控空間之測定	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物理醫學科學					
977.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-9	2014	輪椅－第 9 部：電動輪椅之耐候試驗 (Wheelchairs – Part 9: Climatic tests for electric wheelchairs)	原採認標準
978.	12 Physical Medicine 物理醫學科學	CNS	CNS 15191	2012	木手杖	原採認標準
979.	12 Physical Medicine 物理醫學科學	CNS	CNS 15192	2013	非木質手杖	原採認標準
980.	12 Physical Medicine 物理醫學科學	CNS	CNS 15628-4	2015	輪椅乘坐系統－第 4 部：作為機動車輛之乘坐系統 (Wheelchair seating – Part 4: Seating systems for use in motor vehicles)	原採認標準
981.	12 Physical Medicine 物理醫學科學	CNS	CNS 15910-1	2016	家用之褥瘡防止鋪墊－第 1 部：種類	原採認標準
982.	12 Physical Medicine 物理醫學科學	CNS	CNS 15910-2	2016	家用之褥瘡防止鋪墊－第 2 部：替換靜態型	原採認標準
983.	12 Physical Medicine 物理醫學科學	CNS	CNS 15910-3	2016	家用之褥瘡防止鋪墊－第 3 部：壓力交替型	原採認標準
984.	12 Physical Medicine 物理醫學科學	EN	EN 12183	2022	Manual wheelchairs - Requirements and test methods	原採認標準
985.	12 Physical Medicine 物理醫學科學	EN	EN 12184	2022	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods	原採認標準
986.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-1	2014	Wheelchairs - Part 1: Determination of Static Stability	原採認標準
987.	12 Physical Medicine	ISO	ISO 7176-22	2014	Wheelchairs -- Part 22: Set-up procedures	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	物理醫學科學					
988.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-8	2014	Wheelchairs -- Part 8: Requirements and test methods for static, impact and fatigue strengths	原採認標準
989.	12 Physical Medicine 物理醫學科學	CNS	CNS 16010-1	2017	尿液吸收輔具－詞彙－第 1 部：尿液失禁狀態	原採認標準
990.	12 Physical Medicine 物理醫學科學	CNS	CNS 16010-2	2017	尿液吸收輔具－詞彙－第 2 部：產品	原採認標準
991.	12 Physical Medicine 物理醫學科學	CNS	CNS 16010-3	2017	尿液吸收輔具－詞彙－第 3 部：產品型式識別	原採認標準
992.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-2	2017	Wheelchairs - Part 2: Determination of Dynamic Stability of Electric Wheelchairs	原採認標準
993.	12 Physical Medicine 物理醫學科學	IEC	IEC 60601-2-3	2022	Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of shortwave therapy equipment	原採認標準
994.	12 Physical Medicine 物理醫學科學	IEC	IEC 60601-2-6	2022	Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	原採認標準
995.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-28	2012	Wheelchairs - Part 28: Requirements and test methods for stair-climbing devices	原採認標準
996.	12 Physical Medicine 物理醫學科學	CNS	CNS 14964-28	2016	輪椅－第 28 部：爬梯裝置之要求與測試方法	原採認標準
997.	12 Physical Medicine 物理醫學科學	ISO	ISO 11199-2	2024	Assistive products for walking manipulated by both arms — Requirements and test methods — Part 2: Rollators	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Amendment 1: Removal of brake requirements	
998.	12 Physical Medicine 物理醫學科學	CNS	CNS 16051	2018	具電動輔助起站及坐下機構之座椅與椅座	原採認標準
999.	12 Physical Medicine 物理醫學科學	CNS	CNS 16077	2018	身心障礙者移位用起吊裝置－要求及試驗法	原採認標準
1000.	12 Physical Medicine 物理醫學科學	JSA	JIS D9301	2019	Bicycles For General Use	原採認標準版本更新
1001.	12 Physical Medicine 物理醫學科學	IEC	IEC 80601-2-78	2024	Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation	原採認標準版本更新
1002.	12 Physical Medicine 物理醫學科學	CENELEC	EN IEC 60601-2-83	2021	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	原採認標準
1003.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-25	2025	Wheelchairs — Part 25: Lead-acid batteries and chargers for powered wheelchairs — Requirements and test methods Amendment 1: Range of charging voltage and range of the minimum and maximum rated DC output voltage for testing	原採認標準版本更新
1004.	12 Physical Medicine 物理醫學科學	ISO	ISO 7176-19	2022	Wheelchairs - Part 19: Wheeled mobility devices for use as seats in motor vehicles	原採認標準
1005.	12 Physical Medicine 物理醫學科學	ISO	ISO 11199-3	2005	Walking aids manipulated by both arms — Requirements and test methods — Part 3: Walking	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					tables	
1006.	12 Physical Medicine 物理醫學科學	ISO	ISO 11199-1	2021	Assistive products for walking manipulated by both arms — Requirements and test methods — Part 1: Walking frames	原採認標準
1007.	12 Physical Medicine 物理醫學科學	ISO	ISO 22523	2006	External limb prostheses and external orthoses — Requirements and test methods	原採認標準
1008.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-15	2010	健康資訊交換第七層協定—第 15 部：人事管理	原採認標準
1009.	13 Software/Informatics 軟體/醫療資訊	CLSI	CLSI AUTO02	2006	Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard	原採認標準
1010.	13 Software/Informatics 軟體/醫療資訊	IEC	ISO 25062	2025	Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Common Industry Format (CIF) for reporting usability evaluations	原採認標準版本更新
1011.	13 Software/Informatics 軟體/醫療資訊	CLSI	CLSI AUTO08	2006	Managing and Validating Laboratory Information Systems; Approved Guideline	原採認標準
1012.	13 Software/Informatics 軟體/醫療資訊	CLSI	CLSI AUTO10	2006	Autoverification of Clinical Laboratory Test Results	原採認標準
1013.	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	ANSI AAMI UL 2800-1-3	2022	Standard for Interoperable Item Integration Life Cycle	原採認標準
1014.	13 Software/Informatics 軟體/醫療資訊	ANSI NEMA	ANSI NEMA HN 1	2019	American National Standard Manufacturer Disclosure Statement for Medical Device Security	原採認標準
1015.	13 Software/Informatics 軟體/醫療資訊	CLSI	CLSI AUTO03	2009	Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments,	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Devices, and Information Systems; Approved Standard	
1016.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 80002-1	2009	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software	原採認標準
1017.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-1	2010	健康資訊交換第七層協定—第 1 部：簡介	原採認標準
1018.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-4	2010	健康資訊交換第七層協定—第 4 部：醫囑	原採認標準
1019.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-5	2010	健康資訊交換第七層協定—第 5 部：查詢	原採認標準
1020.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-6	2010	健康資訊交換第七層協定—第 6 部：財務管理	原採認標準
1021.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-7	2010	健康資訊交換第七層協定—第 7 部：觀察報告	原採認標準
1022.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-8	2010	健康資訊交換第七層協定—第 8 部：公用主檔	原採認標準
1023.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-9	2010	健康資訊交換第七層協定—第 9 部：醫療紀錄/資訊管理	原採認標準
1024.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-10	2010	健康資訊交換第七層協定—第 10 部：排程	原採認標準
1025.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-11	2010	健康資訊交換第七層協定—第 11 部：病患轉診	原採認標準
1026.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-12	2010	健康資訊交換第七層協定—第 12 部：病患照護	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1027.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-13	2010	健康資訊交換第七層協定－第 13 部：臨床實驗室 自動化	原採認標準
1028.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-14	2010	健康資訊交換第七層協定－第 14 部：應用管理	原採認標準
1029.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-1	2012	Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples	原採認標準
1030.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-2	2012	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls	原採認標準
1031.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-3	2012	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks	原採認標準
1032.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR80001-2-4	2012	Application of risk management for IT-networks incorporating medical devices — Part 2-4: General implementation guidance for healthcare delivery organizations	原採認標準
1033.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-16	2010	健康資訊交換第七層協定－第 16 部：附錄 (Health Level Seven (HL7) - Part 16: Appendix)	原採認標準
1034.	13 Software/Informatics 軟體/醫療資訊	CNS	CNS 14232-2	2010	健康資訊交換第七層協定－第 2 部：控制 (Health Level Seven (HL7) - Part 2: Control)	原採認標準
1035.	13 Software/Informatics	CNS	CNS 14232-3	2010	健康資訊交換第七層協定－第 3 部：病患管理	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	軟體/醫療資訊				(Health Level Seven (HL7) - Part 3: Patient administration)	
1036.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 62443-2-1	2024	Security for industrial automation and control systems - Part 2-1: Security program requirements for IACS asset owners	原採認標準版本更新
1037.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 80001-1	2021	Application of risk management for IT-networks incorporating medical devices - Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software	原採認標準版本更新
1038.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 62443-3-1	2009	Industrial communication networks—Network and system security—Part 3 – 1: Security technologies for industrial automation and control systems.	原採認標準
1039.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TS 62443-1-1	2009	Industrial communication networks—Network and system security—Part 1 – 1: Terminology, concepts and models	原採認標準
1040.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEC/IEEE 15026-4	2021	Systems and software engineering — Systems and software assurance — Part 4: Assurance in the life cycle	原採認標準
1041.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10404	2022	Health informatics Personal health device communication Part 10404: Device specialization Pulse oximeter	原採認標準
1042.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEC 25001	2014	Systems and software engineering - Systems and software Quality Requirements and Evaluation	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					(SQuaRE) - Planning and management	
1043.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEC 25051	2014	Software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing	原採認標準
1044.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10406	2012	Health informatics--Personal health device communication Part 10406: Device specialization--Basic electrocardiograph (ECG) (1- to 3-lead ECG)	原採認標準
1045.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10408	2022	Health Informatics-Personal Health Device Communication Part 10408: Device Specialization-Thermometer	原採認標準
1046.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10415	2022	Health Informatics-Personal Health Device Communication Part 10415: Device Specialization-Weighing Scale	原採認標準
1047.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10472	2024	Health Informatics—Personal health device communication—Part 10472 Device specialization—Medication monitor	原採認標準版本更新
1048.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 62304	2015	Medical device software - Software life cycle processes	原採認標準
1049.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10407	2022	ISO/IEEE Health informatics Personal health device communication Part 10407: Device specialization Blood pressure monitor	原採認標準
1050.	13 Software/Informatics	ISO	ISO/IEEE	2004	IEEE Standard for Health Informatics -	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	軟體/醫療資訊		11073-20101		Point-Of-Care Medical Device Communication - Part 20101: Application Profile - Base Standard	
1051.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 82304-1	2016	Health software - Part 1: General requirements for product safety	原採認標準
1052.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 80001-2-5	2014	Application of risk management for IT-networks incorporating medical devices - Part 2-5: Application guidance - Guidance on distributed alarm systems	原採認標準
1053.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC/TR 80002-3	2014	Medical device software - Part 3: Process reference model of medical device software life cycle processes (IEC 62304)	原採認標準
1054.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10417	2023	Health Informatics-Personal health device communication Part 10417: Device specialization-Glucose meter	原採認標準
1055.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10422	2016	Health informatics-Personal health device communication Part 10422: Device specialization - Urine analyzer	原採認標準
1056.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10424	2017	Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE)	原採認標準
1057.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 3333.2.1	2015	IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling	原採認標準
1058.	13 Software/Informatics	ISO	ISO/TR	2014	Application of risk management for IT-networks	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	軟體/醫療資訊		80001-2-6		incorporating medical devices — Part 2-6: Application guidance — Guidance for responsibility agreements	
1059.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/TR 80002-2	2017	Medical device software - Part 2: Validation of software for medical device quality systems	原採認標準
1060.	13 Software/Informatics 軟體/醫療資訊	IEEE UL	IEEE UL Std 2621.2	2022	Standard for Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions	原採認標準
1061.	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	ANSI AAMI UL 2800-1	2022	Standard for Medical Device Interoperability	原採認標準
1062.	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	ANSI AAMI UL 2800-1-2	2022	Standard for Interoperable Item Development Life Cycle	原採認標準
1063.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10421	2024	Health informatics — Device interoperability Part 10421: Personal health device communication — Device specialization — Peak expiratory flow monitor (peak flow)	原採認標準版本更新
1064.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 1012	2017	IEEE Standard for System and Software Verification and Validation	原採認標準
1065.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 11073-10425	2023	Health informatics—Personal health device communication Part 10425: Device Specialization—Continuous Glucose Monitor (CGM)	原採認標準
1066.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 11073-20601	2022	Health informatics--Device interoperability--Part 20601: Personal health device communication--Application profile --Optimized	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					exchange protocol	
1067.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE/IEC/ISO 12207	2017	Systems and software engineering -- Software life cycle processes	原採認標準
1068.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10102	2014	Health informatics -- Point-of-care medical device communication Part 10102: Nomenclature --Annotated ECG	原採認標準
1069.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10417	2017	IEEE Health informatics -- Personal health device communication Part 10417: Device Specialization -- Glucose Meter	原採認標準
1070.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR45	2023	Guidance on the use of AGILE practices in the development of medical device software	原採認標準
1071.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI CR34971	2022	Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning	原採認標準
1072.	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI UL	ANSI AAMI UL 2800-1-1	2022	Standard for Risk Concerns for Interoperable Medical Products	原採認標準
1073.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10418	2016	Health informatics—Personal health device communication—Part 10418 Device specialization—International normalized ratio (INR) monitor	原採認標準
1074.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10101	2020	Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature	原採認標準
1075.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10207	2019	Health informatics--Point-of-care medical device communication - Part 10207: Domain Information and Service Model for Service-Oriented	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Point-of-Care Medical Device Communication	
1076.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-20702	2018	Health informatics—Point-of-care medical device communication—Part 20702: Medical devices communication profile for web services	原採認標準
1077.	13 Software/Informatics 軟體/醫療資訊	ISO	ISO/IEEE 11073-10201	2020	Health informatics — Device interoperability Part 10201: Point-of-care medical device communication — Domain information model	原採認標準
1078.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR57	2019	Principles for medical device security—Risk management	原採認標準
1079.	13 Software/Informatics 軟體/醫療資訊	AAMI	AAMI TIR 97	2019	Principles for medical device security—Postmarket risk management for device manufacturers	原採認標準
1080.	13 Software/Informatics 軟體/醫療資訊	ISO/IEC	ISO/IEC 27000	2018	Information technology — Security techniques — Information security management systems — Overview and vocabulary	原採認標準
1081.	13 Software/Informatics 軟體/醫療資訊	ANSI UL	ANSI UL 2900-1	2023	Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements	原採認標準
1082.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-40102	2022	Health informatics--Device interoperability Part 40102: Foundational--Cybersecurity--Capabilities for mitigation	原採認標準版本更新
1083.	13 Software/Informatics 軟體/醫療資訊	ISO/IEC	ISO/IEC 27035-1	2023	Information technology - Information security incident management - Part 1: Principles and process	原採認標準
1084.	13 Software/Informatics 軟體/醫療資訊	ISO/IEC	ISO/IEC 27035-2	2023	Information technology - Information security incident management - Part 2: Guidelines to plan and	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					prepare for incident response	
1085.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC TR 80001-2-8	2016	Application of risk management for IT-networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2	原採認標準
1086.	13 Software/Informatics 軟體/醫療資訊	ANSI UL	ANSI UL 2900-2-1	2017	Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems	原採認標準
1087.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-40101	2022	Health informatics - Device interoperability Part 40101: Foundational - Cybersecurity - Processes for vulnerability assessment.	原採認標準版本更新
1088.	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI	ANSI AAMI 2700-1	2019	Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model	原採認標準
1089.	13 Software/Informatics 軟體/醫療資訊	IEC	IEC 81001-5-1	2021	Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle	原採認標準
1090.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10101b	2023	Health Informatics--Device Interoperability Part 10101: Foundational--Nomenclature Amendment 1: Additional definitions	原採認標準版本更新
1091.	13 Software/Informatics	IEEE	IEEE Std	2024	Health informatics--Device interoperability--Part	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	軟體/醫療資訊		11073-10700		10700: Point-of-care medical device communication--Standard for base requirements for participants in a Service-oriented Device Connectivity (SDC) system	更新
1092.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10206	2022	Health informatics - Device interoperability - Part 10206: Personal health device communication - Abstract Content Information Model	原採認標準
1093.	13 Software/Informatics 軟體/醫療資訊	ISO IEC IEEE	ISO IEC IEEE 29119-1	2022	Software and systems engineering - Software testing - Part 1: General concepts	原採認標準
1094.	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI	ANSI AAMI 2700-2-1	2022	Medical devices and medical systems - Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging	原採認標準
1095.	13 Software/Informatics 軟體/醫療資訊	ANSI AAMI	ANSI AAMI SW96	2023	Standard for medical device security - Security risk management for device manufacturers	原採認標準
1096.	13 Software/Informatics 軟體/醫療資訊	FIRST	FIRST CVSS v4.0	2023	Common Vulnerability Scoring System version 4.0	115 年度新增採 認標準
1097.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE Std 11073-10419	2023	Health informatics - Device Interoperability Part 10419: Personal health device communication - Device Specialization - Insulin Pump	115 年度新增採 認標準
1098.	13 Software/Informatics 軟體/醫療資訊	IEEE	IEEE 11073-10103	2023	Health informatics - Point-of-care medical device communication - Part 10103: Nomenclature - Implantable device cardiac	115 年度新增採 認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1099.	13 Software/Informatics 軟體/醫療資訊	ISO IEEE	ISO IEEE 11073-10701	2024	Health informatics - Device interoperability Part 10701: Point-of-care medical device communication - Metric provisioning by participants in a Service-oriented Device Connectivity (SDC) system	115 年度新增採 認標準
1100.	14 Radiology 放射學 科學	NEMA	DICOM PS3.7	2025	Digital Imaging and Communications in Medicine (DICOM) Part 7: Message Exchange	原採認標準版本 更新
1101.	14 Radiology 放射學 科學	NEMA	DICOM PS3.8	2025	Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange	原採認標準版本 更新
1102.	14 Radiology 放射學 科學	ISO	ISO 13696	2022	Optics and photonics — Test method for total scattering by optical components	原採認標準
1103.	14 Radiology 放射學 科學	IEC	IEC 61847	2025	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics	原採認標準版本 更新
1104.	14 Radiology 放射學 科學	ISO	ISO 11146-2	2021	Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 2: General astigmatic beams	原採認標準
1105.	14 Radiology 放射學 科學	ISO	ISO/TR 11146-3	2005	Lasers and laser-related equipment -- Test methods for laser beam widths, divergence angles and beam propagation ratios -- Part 3: Intrinsic and geometrical laser beam classification, propagation and details of test methods	原採認標準
1106.	14 Radiology 放射學 科學	ISO	ISO 9236-1	2004	Photography - Sensitometry of screen/film systems for medical radiography - Part 1: Determination of	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					sensitometric curve shape, speed and average gradient	
1107.	14 Radiology 放射學 科學	ISO	ISO 4090	2001	Photography - Medical radiographic cassette/screens/films and hard-copy imaging films - Dimensions and specifications	原採認標準
1108.	14 Radiology 放射學 科學	ISO	ISO 5799	1991	Photography -- Direct-exposing medical and dental radiographic film/process systems -- Determination of ISO speed and ISO average gradient	原採認標準
1109.	14 Radiology 放射學 科學	ISO	ISO 15367-1	2003	Lasers and laser-related equipment -- Test methods for determination of the shape of a laser beam wavefront -- Part 1: Terminology and fundamental aspects	原採認標準
1110.	14 Radiology 放射學 科學	IEC	IEC 60825-4	2022	Safety of laser products – Part 4: Laser guards	原採認標準
1111.	14 Radiology 放射學 科學	IEC	IEC 61161	2013	Ultrasonics—Power measurement—Radiation force balances and performance requirements.	原採認標準
1112.	14 Radiology 放射學 科學	IEC	IEC 61217	2011	Radiotherapy equipment – Coordinates, movements and scales	原採認標準
1113.	14 Radiology 放射學 科學	NEMA	DICOM PS3.6	2025	Digital Imaging and Communications in Medicine (DICOM) Part 6: Data Dictionary	原採認標準版本更新
1114.	14 Radiology 放射學 科學	ISO	ISO 15367-2	2005	Lasers and laser-related equipment - Test methods for determination of the shape of a laser beam wavefront - Part 2: Shack-Hartman sensors	原採認標準
1115.	14 Radiology 放射學	IEC	IEC/TR	2022	Safety of laser products - Part 14: A user's guide	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	科學		60825-14			更新
1116.	14 Radiology 放射學 科學	IEC	IEC/TR 60825-8	2022	Safety of laser products - Part 8: Guidelines for the safe use of laser beams on humans	原採認標準
1117.	14 Radiology 放射學 科學	IEC	IEC 60601-2-29	2008	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	原採認標準
1118.	14 Radiology 放射學 科學	ISO	ISO 11670	2004	Lasers and laser-related equipment -- Test methods for laser beam parameters -- Beam positional stability	原採認標準
1119.	14 Radiology 放射學 科學	CNS	CNS 15211	2010	健康資訊學－醫學數位影像及通信暨工作流程及資料處理	原採認標準
1120.	14 Radiology 放射學 科學	IEC	IEC 60601-2-5	2009	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	原採認標準
1121.	14 Radiology 放射學 科學	IEC	IEC/TR 60825-3	2022	Safety of laser products - Part 3: Guidance for laser displays and shows	原採認標準
1122.	14 Radiology 放射學 科學	IEC	IEC 60976	2007	Medical electrical equipment - Medical electron accelerators - Functional performance characteristics	原採認標準
1123.	14 Radiology 放射學 科學	NEMA	DICOM PS3.11	2025	Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles	原採認標準版本 更新
1124.	14 Radiology 放射學 科學	NEMA	DICOM PS3.12	2025	Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange	原採認標準版本 更新
1125.	14 Radiology 放射學	ISO	ISO 21254-3	2011	Lasers and laser-related equipment — Test methods	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	科學				for laser-induced damage threshold — Part 3: Assurance of laser power (energy) handling capabilities	
1126.	14 Radiology 放射學 科學	ISO	ISO TR 21254-4	2011	Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Part 4: Inspection, detection and measurement	原採認標準
1127.	14 Radiology 放射學 科學	CNS	CNS 15584	2013	X 射線管組件之永久過濾測定 (Determination of the permanent filtration of X-ray tube assemblies (IDT: IEC 60522:1999))	原採認標準
1128.	14 Radiology 放射學 科學	CNS	CNS 15586	2013	醫電設備電性安全—醫用診斷 X 射線管組件—焦斑特性 (Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots (IDT: IEC 60336:2005))	原採認標準
1129.	14 Radiology 放射學 科學	CNS	CNS 15587	2013	醫用診斷 X 射線設備—用於測定特性的輻射條件 (Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics (IDT: IEC 61267:2005))	原採認標準
1130.	14 Radiology 放射學 科學	IEC	IEC 60601-1-3	2021	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	原採認標準
1131.	14 Radiology 放射學 科學	IEC	IEC 60601-2-11	2013	Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					equipment	
1132.	14 Radiology 放射學 科學	IEC	IEC 60627	2013	Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids	原採認標準
1133.	14 Radiology 放射學 科學	IEC	IEC 60825-1	2014	Safety of laser products - Part 1: Equipment classification and requirements	原採認標準
1134.	14 Radiology 放射學 科學	IEC	IEC 60825-2	2021	Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCs)	原採認標準
1135.	14 Radiology 放射學 科學	IEC	IEC 61223-3-2	2007	Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment	原採認標準
1136.	14 Radiology 放射學 科學	IEC	IEC 61223-3-4	2000	Evaluation and Routine Testing in Medical Imaging Departments - Part 3-4: Acceptance Tests – Imaging Performance of Dental X-Ray Equipment	原採認標準
1137.	14 Radiology 放射學 科學	IEC	IEC 61331-1	2014	Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials	原採認標準
1138.	14 Radiology 放射學 科學	IEC	IEC 61331-2	2014	Protective devices against diagnostic medical X-radiation – Part 2: Translucent protective plates	原採認標準
1139.	14 Radiology 放射學 科學	IEC	IEC 62083	2009	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	原採認標準
1140.	14 Radiology 放射學 科學	IEC	IEC 62127-1	2022	Ultrasonics—Hydrophones—Part 1: Measurement and characterization of medical ultrasonic fields up to	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					40 megahertz (MHz).	
1141.	14 Radiology 放射學 科學	IEC	IEC 62127-3	2022	Ultrasonics—Hydrophones—Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz.	原採認標準
1142.	14 Radiology 放射學 科學	IEC	IEC 62555	2013	Ultrasonics—Power measurement—High intensity therapeutic ultrasound (HITU) transducers and systems	原採認標準
1143.	14 Radiology 放射學 科學	IEC	IEC 61331-3	2014	Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields	原採認標準
1144.	14 Radiology 放射學 科學	IEC	IEC 61674	2024	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	原採認標準版本 更新
1145.	14 Radiology 放射學 科學	IEC	IEC 61689	2022	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz	原採認標準版本 更新
1146.	14 Radiology 放射學 科學	IEEE	IEEE N42.13	2004	Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides	原採認標準
1147.	14 Radiology 放射學 科學	ISO	ISO 11146-1	2021	Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams	原採認標準
1148.	14 Radiology 放射學 科學	ISO	ISO 21254-1	2011	Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 1: Definitions and general principles	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1149.	14 Radiology 放射學 科學	ISO	ISO 21254-2	2011	Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 2: Threshold determination	原採認標準
1150.	14 Radiology 放射學 科學	ISO	ISO 2919	2012	Radiological protection -- Sealed radioactive sources -- General requirements and classification	原採認標準
1151.	14 Radiology 放射學 科學	ISO	ISO/ASTM 51275	2013	Practice for use of a radiochromic film dosimetry system	原採認標準
1152.	14 Radiology 放射學 科學	ISO	ISO/ASTM 51607	2013	Practice for use of an alanine-EPR dosimetry system	原採認標準
1153.	14 Radiology 放射學 科學	EN	EN 62570	2015	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	原採認標準
1154.	14 Radiology 放射學 科學	ISO	ISO 11551	2019	Optics and optical instruments - Lasers and laser-related equipment - Test method for absorptance of optical laser components	原採認標準
1155.	14 Radiology 放射學 科學	NEMA	DICOM PS3.1	2025	Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview	原採認標準版本更新
1156.	14 Radiology 放射學 科學	NEMA	DICOM PS3.10	2025	Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for Media Interchange	原採認標準版本更新
1157.	14 Radiology 放射學 科學	ASTM	ASTM F2978	2020	Standards Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1158.	14 Radiology 放射學 科學	EN	EN 62220-1-1	2015	Medical electrical equipment - Characteristics of digital x-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging	原採認標準
1159.	14 Radiology 放射學 科學	IEC	IEC 60601-2-1	2020	Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	原採認標準
1160.	14 Radiology 放射學 科學	IEC	IEC 60601-2-17	2013	Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment	原採認標準
1161.	14 Radiology 放射學 科學	IEC	IEC 60601-2-33	2022	Corrigendum 2 - Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	原採認標準
1162.	14 Radiology 放射學 科學	IEC	IEC 60601-2-36	2014	Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy	原採認標準
1163.	14 Radiology 放射學 科學	IEC	IEC 60601-2-37	2024	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1164.	14 Radiology 放射學 科學	IEC	IEC 60601-2-44	2016	Medical electrical equipment Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography - AMD: March 31, 2012; AMD: June 30, 2013; AMD: July 31, 2016	原採認標準
1165.	14 Radiology 放射學 科學	IEC	IEC 60601-2-45	2022	Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	原採認標準
1166.	14 Radiology 放射學 科學	IEC	IEC 60601-2-62	2013	Medical electrical equipment—Part 2 – 62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment	原採認標準
1167.	14 Radiology 放射學 科學	IEC	IEC 60601-2-64	2014	Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment	原採認標準
1168.	14 Radiology 放射學 科學	IEC	IEC 60601-2-68	2025	Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	原採認標準版本 更新
1169.	14 Radiology 放射學	IEC	IEC 60601-2-8	2015	Medical electrical equipment – Part 2-8: Particular	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	科學				requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	
1170.	14 Radiology 放射學 科學	IEC	IEC 60731	2016	Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy	原採認標準
1171.	14 Radiology 放射學 科學	NEMA	DICOM PS3.4	2025	Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications	原採認標準版本更新
1172.	14 Radiology 放射學 科學	NEMA	DICOM PS3.5	2025	Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding	原採認標準版本更新
1173.	14 Radiology 放射學 科學	ISO	ISO 11810	2015	Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Primary ignition, penetration, flame spread and secondary ignition	原採認標準
1174.	14 Radiology 放射學 科學	ISO	ISO/ASTM 51707	2015	Guide for estimating uncertainties in dosimetry for radiation processing	原採認標準
1175.	14 Radiology 放射學 科學	IEC	IEC 60601-2-28	2017	Medical electrical equipment - Part 2-28:Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	原採認標準
1176.	14 Radiology 放射學 科學	IEC	IEC 60601-2-63	2021	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment	原採認標準版本更新
1177.	14 Radiology 放射學	IEC	IEC 60601-2-65	2021	Medical electrical equipment - Part 2-65: Particular	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	科學				requirements for the basic safety and essential performance of dental intra-oral X-ray equipment	更新
1178.	14 Radiology 放射學 科學	ISO	ISO 11554	2025	Optics and photonics — Lasers and laser-related equipment — Test methods for laser beam radiant power, radiant energy and temporal characteristics	原採認標準版本 更新
1179.	14 Radiology 放射學 科學	ISO	ISO 12052	2017	Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management	原採認標準
1180.	14 Radiology 放射學 科學	ASTM	ASTM D7866	2023	Standard Specification for Radiation Attenuating Protective Gloves	原採認標準
1181.	14 Radiology 放射學 科學	ISO	ISO 11990	2018	Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes Part 2: Tracheal tube cuffs	原採認標準
1182.	14 Radiology 放射學 科學	IEC	IEC 60601-2-54	2022	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	原採認標準
1183.	14 Radiology 放射學 科學	IEC	IEC 61223-3-5	2019	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment	原採認標準
1184.	14 Radiology 放射學 科學	IEC	IEC 80601-2-26	2024	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs	原採認標準版本 更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1185.	14 Radiology 放射學 科學	NEMA	DICOM PS3.14	2025	Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function	原採認標準版本更新
1186.	14 Radiology 放射學 科學	NEMA	DICOM PS3.15	2025	Digital Imaging and Communications in Medicine (DICOM) Part 15: Security and System Management Profiles	原採認標準版本更新
1187.	14 Radiology 放射學 科學	NEMA	DICOM PS3.16	2025	Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource	原採認標準版本更新
1188.	14 Radiology 放射學 科學	NEMA	DICOM PS3.17	2025	Digital Imaging and Communications in Medicine (DICOM) Part 17: Explanatory Information	原採認標準版本更新
1189.	14 Radiology 放射學 科學	NEMA	DICOM PS3.18	2025	Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Services	原採認標準版本更新
1190.	14 Radiology 放射學 科學	NEMA	DICOM PS3.19	2025	Digital Imaging and Communications in Medicine (DICOM) Part 19: Application Hosting	原採認標準版本更新
1191.	14 Radiology 放射學 科學	NEMA	DICOM PS3.2	2025	Digital Imaging and Communications in Medicine (DICOM) Part 2: Conformance	原採認標準版本更新
1192.	14 Radiology 放射學 科學	NEMA	DICOM PS3.20	2025	Digital Imaging and Communications in Medicine (DICOM) Part 20: Transformation of DICOM to and from HL7 Standards	原採認標準版本更新
1193.	14 Radiology 放射學 科學	NEMA	DICOM PS3.3	2025	Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions	原採認標準版本更新
1194.	14 Radiology 放射學 科學	IEC	IEC 60601-2-43	2022	Medical electrical equipment - Part 2-43:Particular requirements for the basic safety and essential performance of X-ray equipment for interventional	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					procedures	
1195.	14 Radiology 放射學 科學	IEC	IEC 62471	2006	Photobiological safety of lamps and lamp systems	原採認標準
1196.	14 Radiology 放射學 科學	NEMA	XR 25	2019	Computed Tomography Dose Check	原採認標準
1197.	14 Radiology 放射學 科學	NEMA	NEMA MS 14	2019	Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems	原採認標準
1198.	14 Radiology 放射學 科學	IEC	IEC TR 63183	2019	Guidance on error and warning messages for software used in radiotherapy	原採認標準
1199.	14 Radiology 放射學 科學	AAMI	AAMI RT3	2020	Radiation therapy machine characterization	原採認標準
1200.	14 Radiology 放射學 科學	IEC	IEC 60336	2020	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics	原採認標準
1201.	14 Radiology 放射學 科學	IEC	IEC 62563-1	2021	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	原採認標準
1202.	14 Radiology 放射學 科學	IEC	IEC 61223-3-7	2021	Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography	原採認標準
1203.	14 Radiology 放射學 科學	NEMA	NEMA PS 3.1 - 3.20	2024	Digital Imaging and Communications in Medicine (DICOM) Set	原採認標準
1204.	14 Radiology 放射學 科學	IEC	IEC 62563-2	2021	Medical electrical equipment - Medical image display systems - Part 2: Acceptance and constancy tests for	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					medical image displays	
1205.	14 Radiology 放射學 科學	IEC	IEC 60806	2022	Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis	原採認標準
1206.	14 Radiology 放射學 科學	ISO	ISO 12005	2022	Lasers and laser-related equipment - Test methods for laser beam parameters - Polarization	原採認標準
1207.	14 Radiology 放射學 科學	NEMA	NEMA MS 4	2023	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	原採認標準
1208.	14 Radiology 放射學 科學	IEC	IEC 60601-2-57	2023	Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic diagnostic monitoring cosmetic and aesthetic use	原採認標準
1209.	14 Radiology 放射學 科學	IEC	IEC 60601-2-22	2019	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment	原採認標準
1210.	14 Radiology 放射學 科學	IEC	IEC 63145-10	2023	Eyewear display - Part 10: Specifications	原採認標準
1211.	14 Radiology 放射學 科學	ICDM	ICDM IDMS	2023	Information Display Measurements Standard	原採認標準
1212.	14 Radiology 放射學 科學	ANSI	ANSI Z136.1	2022	American National Standard for Safe Use of Lasers	原採認標準
1213.	14 Radiology 放射學	ISO	ISO 13695	2024	Optics and photonics - Lasers and laser-related	115 年度新增採

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	科學				equipment - Test methods for the spectral characteristics of lasers	認標準
1214.	14 Radiology 放射學 科學	ISO	ISO 14880-2	2024	Optics and photonics -- Microlens arrays -- Part 2: Test methods for wavefront aberrations	115 年度新增採 認標準
1215.	14 Radiology 放射學 科學	ISO	ISO 14880-3	2024	Optics and photonics -- Microlens arrays -- Part 3: Test methods for optical properties other than wavefront aberrations	115 年度新增採 認標準
1216.	14 Radiology 放射學 科學	ISO	ISO 14880-4	2024	Optics and photonics -- Microlens arrays -- Part 4: Test methods for geometrical properties	115 年度新增採 認標準
1217.	14 Radiology 放射學 科學	ISO	ISO 24013	2023	Optics and photonics -- Lasers and laser-related equipment - Measurement of phase retardation of optical components for polarized laser radiation	115 年度新增採 認標準
1218.	14 Radiology 放射學 科學	ANSI UL	ANSI UL 122	2019	Standard for Safety Photographic Equipment - Ed. 5.0 [Including revisions through October 15 2019]	115 年度新增採 認標準
1219.	14 Radiology 放射學 科學	ISO	ISO 12609-1	2021	Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications -- Part 1: Specification for products	115 年度新增採 認標準
1220.	14 Radiology 放射學 科學	IEC	IEC 62127-2	2025	Ultrasonics -- Hydrophones -- Part 2: Calibration for ultrasonic fields up to 40 MHz	115 年度新增採 認標準
1221.	14 Radiology 放射學 科學	NEMA	NEMA NU 2	2024	Performance Measurements of Positron Emission Tomographs	115 年度新增採 認標準
1222.	14 Radiology 放射學 科學	NEMA	NEMA NU 1	2023	Performance Measurements of Gamma Cameras	115 年度新增採 認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1223.	14 Radiology 放射學 科學	IEC	IEC 61223-3-8	2024	Evaluation and routine testing in medical imaging departments - Part 3-8: Acceptance and constancy tests - Imaging performance of X-ray equipment for radiography and radioscopy	115 年度新增採 認標準
1224.	14 Radiology 放射學 科學	IEC	IEC 61223-3-6	2020	Evaluation and routine testing in medical imaging departments - Part 3-6: Acceptance and constancy tests - Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation	115 年度新增採 認標準
1225.	15 Sterility 滅菌	ISO	ISO 14644-4	2022	Cleanrooms and Associated Controlled Environments - Part 4: Design, Construction and Start-up	原採認標準
1226.	15 Sterility 滅菌	ISO	ISO 14698-1	2003	Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods	原採認標準
1227.	15 Sterility 滅菌	ISO	ISO 13408-4	2005	Aseptic processing of health care products —Part 4: Clean-in-place technologies	原採認標準
1228.	15 Sterility 滅菌	ISO	ISO 14644-5	2025	Cleanrooms and associated controlled environments Part 5: Operations	原採認標準版本 更新
1229.	15 Sterility 滅菌	ISO	ISO 11140-5	2007	Sterilization of health care products -- Chemical indicators -- Part 5: Class 2 indicators for Bowie and Dick-type air removal tests	原採認標準
1230.	15 Sterility 滅菌	ISO	ISO 14698-2	2003	Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 2: Evaluation and Interpretation of Biocontamination Data	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1231.	15 Sterility 滅菌	ISO	ISO 14644-7	2004	Cleanrooms and associated controlled environments —Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	原採認標準
1232.	15 Sterility 滅菌	ISO	ISO 11140-3	2007	Sterilization of health care products -- Chemical indicators -- Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	原採認標準
1233.	15 Sterility 滅菌	ISO	ISO 13408-3	2006	Aseptic processing of health care products -- Part 3: Lyophilization	原採認標準
1234.	15 Sterility 滅菌	ISO	ISO 13408-5	2006	Aseptic processing of health care products -- Part 5: Sterilization in place	原採認標準
1235.	15 Sterility 滅菌	ISO	ISO 15882	2008	Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results	原採認標準
1236.	15 Sterility 滅菌	ISO	ISO 11140-4	2007	Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	原採認標準
1237.	15 Sterility 滅菌	CEN	EN 556-1	2024	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices	原採認標準
1238.	15 Sterility 滅菌	ISO	ISO 14937	2009	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					control of a sterilization process for medical devices	
1239.	15 Sterility 滅菌	AOAC	AOAC 6.2.02	2006	Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method	原採認標準
1240.	15 Sterility 滅菌	AOAC	AOAC 6.2.03	2006	Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method	原採認標準
1241.	15 Sterility 滅菌	AOAC	AOAC 6.2.05	2006	Testing Disinfectants Against Pseudomonas aeruginosa, Hard Surface Carrier Test Method.	原採認標準
1242.	15 Sterility 滅菌	AOAC	AOAC 6.3.02	2006	Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes.	原採認標準
1243.	15 Sterility 滅菌	AOAC	AOAC 6.3.05	2012	Sporicidal Activity of Disinfectants Method I.	原採認標準
1244.	15 Sterility 滅菌	AOAC	AOAC 6.3.06	2012	Tuberculocidal Activity of Disinfectants.	原採認標準
1245.	15 Sterility 滅菌	ISO	ISO 11138-3	2017	Sterilization of health care products - Biological indicators Part 3: Biological indicators for moist heat sterilization processes	原採認標準
1246.	15 Sterility 滅菌	ISO	ISO 11138-4	2017	Sterilization of health care products - Biological indicators Part 4: Biological indicators for dry heat sterilization processes	原採認標準
1247.	15 Sterility 滅菌	ISO	ISO 11140-1	2014	Sterilization of health care products -- Chemical indicators -- Part 1: General requirements	原採認標準
1248.	15 Sterility 滅菌	AAMI	ANSI AAMI ST77	2018	Containment devices for reusable medical device sterilization, 2nd ed.	原採認標準
1249.	15 Sterility 滅菌	ISO	ISO 18472	2018	Sterilization of health care products —Biological and chemical indicators —Test equipment	原採認標準
1250.	15 Sterility 滅菌	ISO	ISO 11138-7	2019	Sterilization of health care products — Biological	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					indicators — Part 7: Guidance for the selection, use and interpretation of results	
1251.	15 Sterility 滅菌	CNS	CNS 15449-2	2011	量測、控制及實驗室使用電氣設備安全規定－第 2 部：處理醫用材料及實驗室程序使用蒸汽之高壓滅菌鍋特殊規定 (Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes)	原採認標準
1252.	15 Sterility 滅菌	CNS	CNS 15690	2013	健康照護產品滅菌－用語 (Sterilization of health care products – Vocabulary)	原採認標準
1253.	15 Sterility 滅菌	CNS	CNS 15691-1	2013	健康照護產品之無菌操作－第 1 部：一般要求 Aseptic processing of health care products – Part 1: General requirements (IDE ISO 13408-1:2006)	原採認標準
1254.	15 Sterility 滅菌	CNS	CNS 15691-2	2013	健康照護產品之無菌操作－第 2 部：過濾 Aseptic processing of health care products – Part 2: Filtration (IDE ISO 13408-2:2006)	原採認標準
1255.	15 Sterility 滅菌	CNS	CNS 15691-3	2013	健康照護產品之無菌操作－第 3 部：冷凍乾燥無菌操作 Aseptic processing of health care products – Part 3: Lyophilization (IDE ISO 13408-3:2006)	原採認標準
1256.	15 Sterility 滅菌	CNS	CNS 15691-4	2013	健康照護產品之無菌操作－第 4 部：原地清潔 Aseptic processing of health care products – Part 4: Clean-in-place technologies (IDE ISO 13408-4:2005)	原採認標準
1257.	15 Sterility 滅菌	CNS	CNS 15691-5	2013	健康照護產品之無菌操作－第 5 部：原地滅菌	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Aseptic processing of health care products – Part 5: Sterilization in place (IDE ISO 13408-5:2006)	
1258.	15 Sterility 滅菌	CNS	CNS 15691-6	2013	健康照護產品之無菌操作－第 6 部：隔離裝置系統 Aseptic processing of health care products – Part 6: Isolator systems (IDE ISO 13408-6:2005)	原採認標準
1259.	15 Sterility 滅菌	ISO	ISO 13408-6	2021	Aseptic processing of health care products — Part 6: Isolator systems	原採認標準
1260.	15 Sterility 滅菌	ANSI AAMI	ANSI AAMI ST72	2019	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	原採認標準
1261.	15 Sterility 滅菌	ISO	ISO 14160	2020	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	原採認標準
1262.	15 Sterility 滅菌	ISO	ISO 14644-8	2022	Cleanrooms and associated controlled environments -- Part 8: Classification of air cleanliness by chemical concentration (ACC)	原採認標準
1263.	15 Sterility 滅菌	ISO	ISO/ASTM 52701	2013	Guide for performance characterization of dosimeters and dosimetry systems for use in radiation processing	原採認標準
1264.	15 Sterility 滅菌	AAMI	AAMI TIR35	2016	Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1265.	15 Sterility 滅菌	CNS	CNS 14622-1	2014	健康照護產品滅菌－生物指示劑－第 1 部：一般 (Sterilization of health care products – Biological indicators – Part 1: General requirements)	原採認標準
1266.	15 Sterility 滅菌	CNS	CNS 14622-2	2014	健康照護產品滅菌－生物指示劑－第 2 部：環氧 乙烷滅菌程序之生物指示劑(Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes)	原採認標準
1267.	15 Sterility 滅菌	EN	EN 14180	2025	Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	原採認標準版本 更新
1268.	15 Sterility 滅菌	EN	EN 1422	2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	原採認標準
1269.	15 Sterility 滅菌	ISO	ISO 11138-1	2017	Sterilization of health care products — Biological indicators Part 1: General requirements	原採認標準
1270.	15 Sterility 滅菌	ISO	ISO 11138-2	2017	Sterilization of health care products — Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes	原採認標準
1271.	15 Sterility 滅菌	CNS	CNS 14622-3	2014	健康照護產品滅菌－生物指示劑－第 3 部：濕熱 滅菌程序之生物指示劑(Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes)	原採認標準
1272.	15 Sterility 滅菌	CNS	CNS 14622-4	2014	健康照護產品滅菌－生物指示劑－第 4 部：乾熱	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					滅菌程序之生物指示劑(Sterilization of health care products – Biological indicators – Part 4: Biological indicators for dry heat sterilization processes)	
1273.	15 Sterility 滅菌	CNS	CNS 14622-5	2014	健康照護產品滅菌－生物指示劑－第 5 部：低溫蒸汽及甲醛滅菌程序之生物指示劑(Sterilization of health care products – Biological indicators – Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes)	原採認標準
1274.	15 Sterility 滅菌	CNS	CNS 15758-1	2014	最終滅菌醫療器材之包裝－第 1 部：材料、無菌屏障系統及包裝系統之要求(Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems)	原採認標準
1275.	15 Sterility 滅菌	EN	EN 16615	2015	Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2)	原採認標準
1276.	15 Sterility 滅菌	EN	EN 556-2	2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1277.	15 Sterility 滅菌	ISO	ISO 11138-5	2017	Sterilization of health care products — Biological indicators Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	原採認標準
1278.	15 Sterility 滅菌	ISO	ISO 13408-7	2012	Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products	原採認標準
1279.	15 Sterility 滅菌	ISO	ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	原採認標準
1280.	15 Sterility 滅菌	ISO	ISO 14644-2	2015	Cleanrooms and associated controlled environments Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	原採認標準
1281.	15 Sterility 滅菌	ISO	ISO 20857	2010	Sterilization of health care products_ - Dry heat_ - Requirements for the development, validation and routine control of a sterilization process for medical devices	原採認標準
1282.	15 Sterility 滅菌	ISO	ISO 13408-1	2023	Aseptic processing of health care products Part 1: General requirements	原採認標準
1283.	15 Sterility 滅菌	AAMI	AAMI ST55	2016	Table-Top Steam Sterilizers	原採認標準
1284.	15 Sterility 滅菌	ISO	ISO 11737-1	2018	Sterilization of medical devices -- Microbiological methods -- Part 1:Determination of a population of microorganisms on products	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1285.	15 Sterility 滅菌	ISO	ISO 13408-2	2018	Aseptic Processing of Health Care Products - Part 2: Filtration	原採認標準
1286.	15 Sterility 滅菌	AAMI	AAMI ST50	2018	Dry heat (heated air) sterilizers	原採認標準
1287.	15 Sterility 滅菌	AAMI	AAMI ST8	2018	Hospital steam sterilizers	原採認標準
1288.	15 Sterility 滅菌	AAMI	AAMI ST24	2024	Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	原採認標準
1289.	15 Sterility 滅菌	ASTM	ASTM F2315	2018	Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels	原採認標準
1290.	15 Sterility 滅菌	ASTM	ASTM F2450	2018	Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products	原採認標準
1291.	15 Sterility 滅菌	ISO	ISO 11607-1	2023	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems Amendment 1: Application of risk management	原採認標準版本更新
1292.	15 Sterility 滅菌	ISO	ISO 11607-2	2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes Amendment 1: Application of risk management	原採認標準版本更新
1293.	15 Sterility 滅菌	ISO	ISO 14644-3	2019	Cleanrooms and associated controlled environments —Part 3: Test methods	原採認標準
1294.	15 Sterility 滅菌	ISO	ISO/ASTM 52628	2020	Practice for dosimetry in radiation processing	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

1295.	15 Sterility 滅菌	ISO	ISO 11135	2018	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices Amendment 1: Revision of Annex E, Single batch release	原採認標準
1296.	15 Sterility 滅菌	ISO	ISO 11137-1	2025	Sterilization of health care products — Radiation Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	原採認標準版本更新
1297.	15 Sterility 滅菌	ISO	ISO 11737-2	2019	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	原採認標準
1298.	15 Sterility 滅菌	ASTM ISO	ISO/ASTM 51276	2019	Practice for use of a polymethylmethacrylate dosimetry system	原採認標準
1299.	15 Sterility 滅菌	ASTM	ASTM F2475	2020	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	原採認標準
1300.	15 Sterility 滅菌	ASTM	ASTM F2097	2023	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	原採認標準
1301.	15 Sterility 滅菌	ASTM ISO	ASTM ISO 51818	2020	Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV	原採認標準
1302.	15 Sterility 滅菌	ASTM	ASTM F3004	2020	Standard Test Method for Evaluation of Seal Quality	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					and Integrity Using Airborne Ultrasound	
1303.	15 Sterility 滅菌	ASTM	ASTM F17	2020	Standard Terminology Relating to Flexible Barrier Packaging	原採認標準
1304.	15 Sterility 滅菌	ANSI AAMI	ANSI AAMI ST79	2020	(Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities	原採認標準
1305.	15 Sterility 滅菌	ASTM	ASTM F1608	2021	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	原採認標準
1306.	15 Sterility 滅菌	ASTM	ASTM F88/F88M	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials	原採認標準
1307.	15 Sterility 滅菌	ASTM	ASTM D4169	2023	Standard Practice for Performance Testing of Shipping Containers and Systems	原採認標準
1308.	15 Sterility 滅菌	ANSI AAMI	ANSI AAMI ST91	2021	Flexible and semi-rigid endoscope processing in health care facilities	原採認標準
1309.	15 Sterility 滅菌	CEN	EN 285	2021	Sterilization - Steam sterilizers - Large sterilizers	原採認標準
1310.	15 Sterility 滅菌	AAMI	AAMI TIR28	2016	Product Adoption And Process Equivalence For Ethylene Oxide Sterilization	原採認標準
1311.	15 Sterility 滅菌	ANSI AAMI	ANSI AAMI 13959	2014	Water For Hemodialysis and Related Therapies	原採認標準
1312.	15 Sterility 滅菌	ISO	ISO 11138-8	2021	Sterilization of health care products - Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator	原採認標準
1313.	15 Sterility 滅菌	ISO	ISO 17664-2	2021	Processing of health care products - Information to be	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.	
1314.	15 Sterility 滅菌	ISO	ISO 17664-1	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices	原採認標準
1315.	15 Sterility 滅菌	CEN	EN ISO 17664-1	2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)	原採認標準
1316.	15 Sterility 滅菌	AAMI	AAMI TIR43	2021	Ultrapure Dialysate For Hemodialysis And Related Therapies	原採認標準
1317.	15 Sterility 滅菌	CEN	EN ISO 25424	2022	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 1	原採認標準
1318.	15 Sterility 滅菌	ISO	ISO 22441	2022	Sterilization of health care products - Low temperature vaporized hydrogen peroxide - Requirements for the development validation and routine control of a sterilization process for medical devices	原採認標準
1319.	15 Sterility 滅菌	AAMI	AAMI TIR17	2024	Compatibility of materials subjected to sterilization	原採認標準版本

115 年度衛生福利部食品藥物管理署採認醫療器材標準

						更新
1320.	15 Sterility 滅菌	ASTM	ASTM F2391	2022	Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas	原採認標準
1321.	15 Sterility 滅菌	ISO	ISO TS 16775	2021	Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	原採認標準
1322.	15 Sterility 滅菌	ASTM	ASTM F2638	2022	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier	原採認標準
1323.	15 Sterility 滅菌	ISO	ISO 11137-2	2022	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	原採認標準
1324.	15 Sterility 滅菌	ISO	ISO TS 11137-4	2020	Sterilization of health care products - Radiation - Part 4: Guidance on process control	原採認標準
1325.	15 Sterility 滅菌	ANSI AAMI	ANSI AAMI ST98	2022	Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices	原採認標準
1326.	15 Sterility 滅菌	ASTM	ASTM F1980	2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	原採認標準
1327.	15 Sterility 滅菌	AAMI	AAMI TIR104	2022	Guidance on transferring health care products between radiation sterilization sources	原採認標準
1328.	15 Sterility 滅菌	ISO	ISO 14644-9	2022	Cleanrooms and associated controlled environments - Part 9: Assessment of surface cleanliness for particle concentration	原採認標準
1329.	15 Sterility 滅菌	ASTM	ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Porous Medical Packaging by Dye Penetration	
1330.	15 Sterility 滅菌	AAMI	AAMI TIR12	2023	Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers	原採認標準
1331.	15 Sterility 滅菌	ISO	ISO 14644-10	2022	Cleanrooms and associated controlled environments - Part 10: Assessment of surface cleanliness for chemical contamination	原採認標準
1332.	15 Sterility 滅菌	ASTM	ASTM F3039	2023	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration	原採認標準
1333.	15 Sterility 滅菌	AAMI ANSI	AAMI ANSI ST108	2023	Water for the processing of medical devices	原採認標準
1334.	15 Sterility 滅菌	ISO	ISO 17665	2024	Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	原採認標準
1335.	15 Sterility 滅菌	ANSI AAMI	ANSI AAMI ST58	2024	Chemical sterilization and high-level disinfection in health care facilities	115 年度新增採 認標準
1336.	15 Sterility 滅菌	AAMI	AAMI TIR106	2024	Microbiological methods - Understanding and use of product bioburden data	115 年度新增採 認標準
1337.	15 Sterility 滅菌	ISO	ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial endotoxin testing	115 年度新增採 認標準
1338.	15 Sterility 滅菌	ISO	ISO 13004	2022	Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method	115 年度新增採 認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					VDmaxSD	
1339.	16 Tissue Engineering 組織工程	ASTM	ASTM F2603	2020	Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds	原採認標準
1340.	16 Tissue Engineering 組織工程	ISO	ISO 22442-2	2020	Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling	原採認標準
1341.	16 Tissue Engineering 組織工程	ISO	ISO 22442-3	2007	Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents	原採認標準
1342.	16 Tissue Engineering 組織工程	ASTM	ASTM F3206	2017	Standard Guide for Assessing Medical Device Cytocompatibility with Delivered Cellular Therapies	原採認標準
1343.	16 Tissue Engineering 組織工程	ASTM	ASTM F3207	2017	Standard Guide for in vivo Evaluation of Rabbit Lumbar Intertransverse Process Spinal Fusion Model	原採認標準
1344.	16 Tissue Engineering 組織工程	ASTM	ASTM F3224	2017	Standard Test Method for Evaluating Growth of Engineered Cartilage Tissue using Magnetic Resonance Imaging.	原採認標準
1345.	16 Tissue Engineering 組織工程	ASTM	ASTM F2064	2017	Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Products Application	原採認標準
1346.	16 Tissue Engineering 組織工程	ASTM	ASTM F2212	2025	Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical	原採認標準版本更新

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					Products (TEMPs)	
1347.	16 Tissue Engineering 組織工程	ASTM	ASTM F2150	2019	Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Regenerative Medicine and Tissue-Engineered Medical Products	原採認標準
1348.	16 Tissue Engineering 組織工程	ASTM	ASTM F2739	2019	Standard Guide for Quantifying Cell Viability and Related Attributes within Biomaterial Scaffolds	原採認標準
1349.	16 Tissue Engineering 組織工程	ISO	ISO 22442-1	2020	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	原採認標準
1350.	17 Neurology 神經科學	ISO	ISO 7197	2024	Neurosurgical implants — Sterile, single-use hydrocephalus shunts	原採認標準
1351.	17 Neurology 神經科學	IEC	IEC 60601-2-23	2011	Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment	原採認標準
1352.	17 Neurology 神經科學	IEC	IEC 60601-2-10	2023	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
1353.	17 Neurology 神經科學	ASTM	ASTM F647	2022	Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application	原採認標準
1354.	17 Neurology 神經科學	AAMI	AAMI NS4	2017	Transcutaneous electrical nerve stimulators	原採認標準
1355.	17 Neurology 神經科學	IEEE	IEEE Std 2010	2023	Recommended Practice for Electroencephalography	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	學				(EEG) Neurofeedback Systems	
1356.	17 Neurology 神經科學	ISO	ISO 80601-2-85	2021	Medical electrical equipment - Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment	原採認標準
1357.	17 Neurology 神經科學	IEC	IEC 60601-2-40	2024	Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	115 年度新增採認標準
1358.	18 Nanotechnology 奈米科技	ISO	ISO 29701	2010	Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems—Limulus amoebocyte lysate (LAL) test.	原採認標準
1359.	18 Nanotechnology 奈米科技	ISO	ISO/TR 13014	2012	Nanotechnologies—Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment	原採認標準
1360.	18 Nanotechnology 奈米科技	ISO	ISO 21363	2020	Nanotechnologies - Measurements of particle size and shape distributions by transmission electron microscopy	原採認標準
1361.	18 Nanotechnology 奈米科技	ASTM	ASTM E3247	2020	Standard Test Method for Measuring the Size of Nanoparticles in Aqueous Media Using Dynamic Light Scattering	原採認標準
1362.	18 Nanotechnology 奈米科技	ISO	ISO 19749	2021	Nanotechnologies - Measurements of particle size and shape distributions by scanning electron microscopy	原採認標準
1363.	18 Nanotechnology 奈米科技	ASTM	ASTM E3025	2022	Standard Guide for Tiered Approach to Detection and	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	米科技				Characterization of Silver Nanomaterials in Textiles	
1364.	18 Nanotechnology 奈米科技	ISO	ISO TS 80004-6	2021	Nanotechnologies - Vocabulary - Part 6: Nano-object characterization	原採認標準
1365.	18 Nanotechnology 奈米科技	ISO	ISO 17200	2020	Nanotechnology - Nanoparticles in powder form - Characteristics and measurements	原採認標準
1366.	18 Nanotechnology 奈米科技	ASTM	ASTM E3275	2021	Standard Guide for Visualization and Identification of Nanomaterials in Biological and Nonbiological Matrices Using Darkfield Microscopy/Hyperspectral Imaging (DFM/HSI) Analysis	原採認標準
1367.	18 Nanotechnology 奈米科技	ASTM	ASTM E2524	2022	Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles	原採認標準
1368.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	BS EN	BS EN 50637	2017	Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children	原採認標準
1369.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	CNS	CNS 14912	2005	醫電設備之安全標準規範 (Fundamental aspects of safety standards for medical electrical equipment)	原採認標準
1370.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	CNS	CNS 14913	2005	醫電設備之圖形符號 (Graphical symbols for electrical equipment in medical practice)	原採認標準
1371.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEEE ANSI	IEEE ANSI USEMCSC C63.27	2021	American National Standard for Evaluation of Wireless Coexistence	原採認標準
1372.	19 General II (ES/EMC)	IEC	IEC 60601-1-2	2020	Medical electrical equipment - Part 1-2: General	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	通用(醫療電子/電磁相容)				requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	
1373.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-6	2020	Amendment 2 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	原採認標準
1374.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-8	2020	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	原採認標準
1375.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 61326-1	2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	原採認標準
1376.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-10	2020	Amendment 2 - Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	原採認標準
1377.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-11	2020	Amendment 1 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

					medical electrical systems used in the home healthcare environment	
1378.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1-12	2020	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	原採認標準
1379.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC/TR 62354	2014	General testing procedures for medical electrical equipment	原採認標準
1380.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ANSI UL	ANSI UL 61010-1	2024	Standard for Safety Requirements for Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements	原採認標準版本更新
1381.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC TR 60601-4-2	2024	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	原採認標準
1382.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC/TR 60601-4-1	2017	Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy	原採認標準
1383.	19 General II (ES/EMC) 通用(醫療電子/電磁相	ANSI AAMI	ANSI AAMI ES60601-1	2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential	原採認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	容)				performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]	
1384.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ANSI AAMI	ANSI AAMI HA60601-1-11	2021	Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]	原採認標準
1385.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	ISO	ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer	原採認標準
1386.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	AIM	AIM Standard 7351731	2021	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard	原採認標準
1387.	19 General II (ES/EMC) 通用(醫療電子/電磁相容)	IEC	IEC 60601-1	2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.	原採認標準
1388.	19 General II (ES/EMC) 通用(醫療電子/電磁相	IEC	IEC 60086-5	2021	Primary batteries - Part 5: Safety of batteries with aqueous electrolyte [Including: Corrigendum 1	115 年度新增採 認標準

115 年度衛生福利部食品藥物管理署採認醫療器材標準

	容)				(2022)]	
1389.	19 General II (ES/EMC) 通用(醫療電子/電磁相 容)	IEC	IEC 62133-2	2021	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems	115 年度新增採 認標準
1390.	19 General II (ES/EMC) 通用(醫療電子/電磁相 容)	IEC	IEC 60086-4	2025	Primary batteries - Part 4: Safety of lithium batteries	115 年度新增採 認標準
1391.	19 General II (ES/EMC) 通用(醫療電子/電磁相 容)	UL	UL 1642	2020	Standard For Safety Lithium Batteries	115 年度新增採 認標準
1392.	19 General II (ES/EMC) 通用(醫療電子/電磁相 容)	UL	UL 2054	2021	Standard For Safety Household and Commercial Batteries	115 年度新增採 認標準
1393.	19 General II (ES/EMC) 通用(醫療電子/電磁相 容)	IEC	IEC TS 60601-4-6	2024	Medical electrical equipment - Part 4-6: Guidance and interpretation - Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances	115 年度新增採 認標準