

110 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、110 年度醫療器材標準採認清單(共 1,081 項)

| 序號 | 標準類別 | TFDA 採認編號 | 標準組織名稱 | 標準號碼 | 版本/年份 | 標準名稱 | 備註說明 |
|----|--------------------|------------|--------|---------------------|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 1 | Anesthesias 麻醉學 | TFDA-02106 | ISO | ISO 13320:2020 | 2020 | Particle size analysis — Laser diffraction methods | 110 年度新增採認標準 |
| 2 | Anesthesias 麻醉學 | TFDA-00408 | ISO | ISO 80601-2-84:2020 | 2020 | 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 |
| 3 | Anesthesias 麻醉學 | TFDA-00409 | ISO | ISO 10651-4:2002 | 2002 | Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators | 原採認標準 |
| 4 | Anesthesias 麻醉學 | TFDA-00410 | ISO | ISO 10651-5:2006 | 2006 | Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5: Gas powered emergency resuscitators | 原採認標準 |
| 5 | Anesthesias 麻醉學 | TFDA-00569 | CNS | CNS 14961 | 2005 | 小型醫療氣體鋼瓶－銷針標示軛式閥接頭 | 原採認標準 |
| 6 | Anesthesias 麻醉學 | TFDA-00570 | CNS | CNS 14962 | 2005 | 氣體鋼瓶－工業與醫療氣體鋼瓶之閥保護帽與閥保護套－設計、結構與試驗 | 原採認標準 |
| 7 | Anesthesias 麻醉學 | TFDA-00571 | CNS | CNS 14963 | 2005 | 醫療用氣體混合器－獨立式氣體混合器 | 原採認標準 |
| 8 | Anesthesias | TFDA-00574 | CNS | CNS 15004 | 2006 | 醫療氣體管線系統使用之氧氣濃縮機 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 麻醉學 | | | | | | |
| 9 | Anesthesias 麻醉學 | TFDA-00577 | CNS | CNS 15006 | 2006 | 連接於醫療氣體管線系統終端單元之流量計裝置 | 原採認標準 |
| 10 | Anesthesias 麻醉學 | TFDA-00727 | ISO | ISO 5362:2006 | 2006 | Anaesthetic reservoir bags | 原採認標準 |
| 11 | Anesthesias 麻醉學 | TFDA-01156 | CNS | CNS 14776 | 2003 | 醫用面罩對合成血液穿透阻力的試驗法—以已知速度定量的水平噴灑 (Method of test for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)) | 原採認標準 |
| 12 | Anesthesias 麻醉學 | TFDA-01157 | CNS | CNS 14777 | 2003 | 醫用面罩空氣交換壓力之試驗法 (Method of test for air exchange pressure of medical face mask) | 原採認標準 |
| 13 | Anesthesias 麻醉學 | TFDA-01158 | CNS | CNS 6636 | 2013 | 呼吸防護裝置-氣體濾材及組合型濾材-要求、試驗、標示 (Respiratory protective devices - Gas filters and combined filters - Requirements, testing, marking) | 原採認標準 |
| 14 | Anesthesias 麻醉學 | TFDA-01167 | ISO | ISO 23328-1:2003 | 2003 | Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance | 原採認標準 |
| 15 | Anesthesias 麻醉學 | TFDA-01168 | ISO | ISO 23328-2:2002 | 2002 | Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects | 原採認標準 |
| 16 | Anesthesias 麻醉學 | TFDA-01170 | ISO | ISO 26782:2009/Cor1:2009 | 2009 | Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 17 | Anesthesias 麻醉學 | TFDA-01452 | ASTM | ASTM G175-13 | 2013 | Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications | 原採認標準 |
| 18 | Anesthesias 麻醉學 | TFDA-01454 | ISO | ISO 10079-2:2014 | 2014 | Medical suction equipment - Part 2: Manually powered suction equipment | 原採認標準 |
| 19 | Anesthesias 麻醉學 | TFDA-01455 | ISO | ISO 10079-3:2014 | 2014 | Medical suction equipment Part 3: Suction equipment powered from a vacuum or pressure source | 原採認標準 |
| 20 | Anesthesias 麻醉學 | TFDA-01456 | ISO | ISO 14408:2016 | 2016 | Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information | 原採認標準 |
| 21 | Anesthesias 麻醉學 | TFDA-01457 | ISO | ISO 23747:2015 | 2015 | Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans | 原採認標準 |
| 22 | Anesthesias 麻醉學 | TFDA-01459 | ISO | ISO 5360:2016 | 2016 | Anaesthetic vaporizers - Agent-specific filling systems | 原採認標準 |
| 23 | Anesthesias 麻醉學 | TFDA-01460 | ISO | ISO 5361:2016 | 2016 | Anaesthetic and respiratory equipment — Tracheal tubes and connectors | 原採認標準 |
| 24 | Anesthesias 麻醉學 | TFDA-01461 | ISO | ISO 5364:2016 | 2016 | Anaesthetic and respiratory equipment - Oropharyngeal airways | 原採認標準 |
| 25 | Anesthesias 麻醉學 | TFDA-01462 | ISO | ISO 5366:2016 | 2016 | Anaesthetic and respiratory equipment - Tracheostomy tubes and connectors | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 26 | Anesthesias 麻醉學 | TFDA-01463 | ISO | ISO 5367:2014 | 2014 | Breathing Tubes intended for use with Anaesthetic Apparatus and Ventilators | 原採認標準 |
| 27 | Anesthesias 麻醉學 | TFDA-01464 | ISO | ISO 7376:2020 | 2020 | Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation | 原採認標準 |
| 28 | Anesthesias 麻醉學 | TFDA-01465 | ISO | ISO 80369-7:2021 | 2021 | Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications | 原採認標準 |
| 29 | Anesthesias 麻醉學 | TFDA-01467 | ISO | ISO 80601-2-67:2020 | 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 | Anesthesias 麻醉學 | TFDA-01468 | ISO | ISO 80601-2-69:2020 | 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 | Anesthesias 麻醉學 | TFDA-01765 | ISO | ISO 10524-1: 2018 | 2018 | Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow-metering devices | 原採認標準 |
| 32 | Anesthesias 麻醉學 | TFDA-01766 | ISO | ISO 10524-2: 2018 | 2018 | Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators | 原採認標準 |
| 33 | Anesthesias 麻醉學 | TFDA-01767 | ISO | ISO 17510:2015 | 2015 | Medical devices - Sleep apnoea breathing therapy - Masks and application accessories | 原採認標準 |
| 34 | Anesthesias 麻醉學 | TFDA-01768 | ISO | ISO 5356-1:2015 | 2015 | Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 35 | Anesthesias 麻醉學 | TFDA-01770 | ISO | ISO 5359:2014/AMD 1:2017 | 2017 | Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases | 原採認標準 |
| 36 | Anesthesias 麻醉學 | TFDA-01771 | ISO | ISO 80601-2-55:2018 | 2018 | Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors | 原採認標準 |
| 37 | Anesthesias 麻醉學 | TFDA-01772 | ISO | ISO 80601-2-70:2020 | 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 | Anesthesias 麻醉學 | TFDA-01773 | ISO | ISO 80601-2-74:2017 | 2017 | Medical electrical equipment—Part 2–74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment | 原採認標準 |
| 39 | Anesthesias 麻醉學 | TFDA-01873 | ISO | ISO 10079-1:2015/A MD 1:2018 | 2018 | Medical suction equipment Part 1: Electrically powered suction equipment - Safety requirements | 原採認標準 |
| 40 | Anesthesias 麻醉學 | TFDA-01874 | ISO | ISO 80601-2-13:2011/ Amd 2:2018 | 2011 | Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation | 原採認標準 |
| 41 | Anesthesias 麻醉學 | TFDA-01930 | EN | EN ISO 27427 : 2019 | 2019 | Anaesthetic and respiratory equipment - Nebulizing systems and components | 原採認標準 |
| 42 | Anesthesias 麻醉學 | TFDA-01931 | ISO | ISO 10524-3:2019 | 2019 | Pressure regulators for use with medical gases – Part 3:Pressure regulators integrated with cylinder valves | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 43 | Anesthesias 麻醉學 | TFDA-01932 | ISO | ISO 80369-1:2018 | 2018 | Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements | 原採認標準 |
| 44 | Anesthesias 麻醉學 | TFDA-01934 | ISO | ISO 80601-2-12:2020 | 2020 | Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators | 原採認標準 |
| 45 | Anesthesias 麻醉學 | TFDA-01935 | ISO | ISO 8836:2019 | 2019 | Suction catheters for use in the respiratory tract | 原採認標準 |
| 46 | Anesthesias 麻醉學 | TFDA-01936 | ISO | ISO 5356-2:2012/AM D 1:2019 | 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 | TFDA-02107 | ISO | ISO 26825 Second edition 2020-10 | 2020 | Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours design and performance | 110 年度新增採認標準 |
| 48 | Biocompatibility 生物相容性 | TFDA-00021 | ISO | ISO 10993-14:2001 | 2001 | Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics | 原採認標準 |
| 49 | Biocompatibility 生物相容性 | TFDA-00024 | ISO | ISO 10993-17:2002 | 2002 | Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances | 原採認標準 |
| 50 | Biocompatibility 生物相容性 | TFDA-00234 | CNS | CNS 14393-7 | 2005 | 醫療器材生物性評估－第7部：環氧乙烷滅菌之殘留物 Biological evaluation of medical devices - Part 7: ethylene oxide sterilisation residuals | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 51 | Biocompatibility 生物相容性 | TFDA-00235 | CNS | CNS 14393-8 | 2005 | 醫療器材生物性評估－第 8 部：生物測試用參考材料之選擇及資格認定 Biological evaluation of medical devices - Part 8: Selection and qualification of reference materials for biological tests (ISO 10993-8:2000) | 原採認標準 |
| 52 | Biocompatibility 生物相容性 | TFDA-00236 | CNS | CNS 14393-10 | 2005 | 醫療器材生物性評估－第 10 部：刺激性及延遲型過敏性測試 Biological evaluation of medical devices - Part 10 : tests for irritation and sensitisation | 原採認標準 |
| 53 | Biocompatibility 生物相容性 | TFDA-00237 | CNS | CNS 14393-12 | 2005 | 醫療器材生物性評估－第 12 部：樣品製備及參考材料 Biological evaluation of medical devices - Part 12 : sample preparation and reference materials | 原採認標準 |
| 54 | Biocompatibility 生物相容性 | TFDA-00238 | CNS | CNS 14393-6 | 2004 | 醫療器材生物性評估－第六部分:植入後的局部效應測試 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation | 原採認標準 |
| 55 | Biocompatibility 生物相容性 | TFDA-00239 | CNS | CNS 14393-11 | 2005 | 醫療器材生物性評估－第 11 部：全身毒性測試 Biological evaluation of medical devices - Part 11: tests for systemic toxicity | 原採認標準 |
| 56 | Biocompatibility 生物相容性 | TFDA-00348 | ISO | ISO/TS 10993-20:2006 | 2006 | Biological evaluation of medical devices —Part 20: Principles and methods for immunotoxicology testing of medical devices | 原採認標準 |
| 57 | Biocompatibility 生物相容性 | TFDA-00361 | ISO | ISO 10993-2:2006 | 2006 | Biological evaluation of medical devices -- Part 2: Animal welfare requirements | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 58 | Biocompatibility 生物相容性 | TFDA-00363 | CNS | CNS14393-1 | 2004 | 醫療器材生物性評估-第一部份：評估與試驗 | 原採認標準 |
| 59 | Biocompatibility 生物相容性 | TFDA-00364 | CNS | CNS14393-2 | 2004 | 醫療器材生物性評估-第二部份：動物福利之規定 | 原採認標準 |
| 60 | Biocompatibility 生物相容性 | TFDA-00365 | CNS | CNS14393-3 | 2004 | 醫療器材生物性評估-第三部份：基因毒性、致癌性與生殖毒性之試驗 | 原採認標準 |
| 61 | Biocompatibility 生物相容性 | TFDA-00366 | CNS | CNS14393-4 | 2004 | 醫療器材生物性評估-第四部份：血液接觸特性測試方法的選擇 | 原採認標準 |
| 62 | Biocompatibility 生物相容性 | TFDA-00367 | CNS | CNS14393-5 | 2004 | 醫療器材生物性評估-第五部份：體外細胞毒性試驗 | 原採認標準 |
| 63 | Biocompatibility 生物相容性 | TFDA-00368 | CNS | CNS14393-9 | 2005 | 醫療器材生物性評估-第九部份：潛在降解產物之鑑別與定量分析架構 | 原採認標準 |
| 64 | Biocompatibility 生物相容性 | TFDA-00369 | CNS | CNS14393-13 | 2005 | 醫療器材生物性評估-第十三部份：聚合物醫療器材降解產物之鑑別與定量 | 原採認標準 |
| 65 | Biocompatibility 生物相容性 | TFDA-00370 | CNS | CNS14393-14 | 2005 | 醫療器材生物性評估-第十四部份：陶瓷降解產物之鑑別與定量 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 66 | Biocompatibility 生物相容性 | TFDA-00371 | CNS | CNS14393-15 | 2006 | 醫療器材生物性評估-第十五部份：金屬集合金之降解產物的鑑別與定量 | 原採認標準 |
| 67 | Biocompatibility 生物相容性 | TFDA-00372 | CNS | CNS14393-16 | 2006 | 醫療器材生物性評估-第十六部份：降解及可溶出物之毒性動力學之研究設計 | 原採認標準 |
| 68 | Biocompatibility 生物相容性 | TFDA-00743 | CNS | CNS 15153 | 2007 | 醫療器材生物性評估－第 17 部：可溶出物質容忍限量之建立 | 原採認標準 |
| 69 | Biocompatibility 生物相容性 | TFDA-00744 | CNS | CNS 15154 | 2007 | 醫療器材生物性評估－第 18 部：材料之化學特性 | 原採認標準 |
| 70 | Biocompatibility 生物相容性 | TFDA-00745 | CNS | CNS 15155 | 2007 | 醫療器材生物性評估－第 19 部：材料之物理化學、形態及拓撲學的特性分析 | 原採認標準 |
| 71 | Biocompatibility 生物相容性 | TFDA-00746 | CNS | CNS 14393-20 | 2009 | 醫療器材生物性評估－第 20 部：醫療器材免疫毒理學試驗之原理與方法 | 原採認標準 |
| 72 | Biocompatibility 生物相容性 | TFDA-00858 | ISO | ISO 10993-5:2009 | 2009 | Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity | 原採認標準 |
| 73 | Biocompatibility 生物相容性 | TFDA-00860 | ISO | ISO 10993-13:2010 | 2010 | Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 74 | Biocompatibility 生物相容性 | TFDA-00862 | ISO | ISO 10993-10:2010 | 2010 | Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization | 原採認標準 |
| 75 | Biocompatibility 生物相容性 | TFDA-01022 | ASTM | ASTM F750 - 20 | 2020 | Standard Practice for Evaluating Acute Systemic Toxicity of Material Extracts by Systemic Injection in the Mouse | 原採認標準 |
| 76 | Biocompatibility 生物相容性 | TFDA-01023 | ASTM | ASTM F813 - 20 | 2020 | Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices | 原採認標準 |
| 77 | Biocompatibility 生物相容性 | TFDA-01024 | ISO | ISO 10993-12:2021 | 2021 | Biological evaluation of medical devices — Part 12: Sample preparation and reference materials | 原採認標準 |
| 78 | Biocompatibility 生物相容性 | TFDA-01471 | ISO | ISO 10993-3:2014 | 2014 | Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity | 原採認標準 |
| 79 | Biocompatibility 生物相容性 | TFDA-01472 | ISO | ISO 10993-6:2016 | 2016 | Biological evaluation of medical devices, Part 6: Tests for local effects after implantation | 原採認標準 |
| 80 | Biocompatibility 生物相容性 | TFDA-01473 | ISO | AAMI/ISO TIR37137:2014 | 2014 | Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants | 原採認標準 |
| 81 | Biocompatibility 生物相容性 | TFDA-01474 | ISO | ISO/TR 10993-33 :2015 | 2015 | Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3 - First Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 82 | Biocompatibility 生物相容性 | TFDA-01775 | ASTM | ASTM F720-17 | 2017 | Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test | 原採認標準 |
| 83 | Biocompatibility 生物相容性 | TFDA-01776 | ISO | ISO 10993-11:2017 | 2017 | Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity | 原採認標準 |
| 84 | Biocompatibility 生物相容性 | TFDA-01777 | ISO | ISO 10993-16:2017 | 2017 | Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables | 原採認標準 |
| 85 | Biocompatibility 生物相容性 | TFDA-01778 | ISO | ISO 10993-4:2017 | 2017 | Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood | 原採認標準 |
| 86 | Biocompatibility 生物相容性 | TFDA-01779 | ISO | ISO 18562-1:2017 | 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process | 原採認標準 |
| 87 | Biocompatibility 生物相容性 | TFDA-01780 | ISO | ISO 18562-2:2017 | 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter | 原採認標準 |
| 88 | Biocompatibility 生物相容性 | TFDA-01781 | ISO | ISO 18562-3:2017 | 2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs) | 原採認標準 |
| 89 | Biocompatibility 生物相容性 | TFDA-01782 | ISO | ISO | 2017 | Biocompatibility evaluation of breathing gas | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | lity 生物相容性 | | | 18562-4:2017 | | pathways in healthcare applications - Part 4: Tests for leachables in condensate | |
| 90 | Biocompatibility 生物相容性 | TFDA-01875 | ASTM | ASTM F2382 - 18 | 2018 | Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT) | 原採認標準 |
| 91 | Biocompatibility 生物相容性 | TFDA-01937 | ISO | ISO 10993-1:2018 | 2018 | Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process | 原採認標準 |
| 92 | Biocompatibility 生物相容性 | TFDA-01938 | ASTM | ASTM F2148-18 | 2018 | Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA) | 原採認標準 |
| 93 | Biocompatibility 生物相容性 | TFDA-01939 | ISO | ISO 10993-15:2019 | 2019 | Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals and | 原採認標準 |
| 94 | Biocompatibility 生物相容性 | TFDA-01940 | ISO | ISO 10993-18:2020 | 2020 | Biological evaluation of medical devices —Part 18: Chemical characterization of materials | 原採認標準 |
| 95 | Biocompatibility 生物相容性 | TFDA-01941 | ISO | ISO/TS 10993-19:2020 | 2020 | Biological evaluation of medical devices —Part 19: Physico-chemical, morphological and topographical characterization of materials | 原採認標準 |
| 96 | Biocompatibility 生物相容性 | TFDA-01942 | ISO | ISO 10993-9:2019 | 2019 | Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products | 原採認標準 |
| 97 | Biocompatibility | TFDA-01943 | ASTM | ASTM F719 - 20 | 2020 | Standard Practice for Testing Biomaterials in | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | lity 生物相容性 | | | | | Rabbits for Primary Skin Irritation | |
| 98 | Biocompatibility 生物相容性 | TFDA-01944 | ASTM | ASTM F749 - 20 | 2020 | Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit | 原採認標準 |
| 99 | Biocompatibility 生物相容性 | TFDA-01945 | ISO | ISO 10993-7:2008/Amendment 1:2019 | 2019 | Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals | 原採認標準 |
| 100 | Biocompatibility 生物相容性 | TFDA-02108 | ASTM | ASTM F619-20 | 2020 | Standard Practice for Extraction of Materials Used in Medical Devices | 110 年度新增採認標準 |
| 101 | Biocompatibility 生物相容性 | TFDA-02109 | ASTM | ASTM F1408-20a | 2020 | Standard Practice for Subcutaneous Screening Test for Implant Materials | 110 年度新增採認標準 |
| 102 | Biocompatibility 生物相容性 | TFDA-02110 | CEN ISO | EN ISO 10993-23:2021 | 2021 | Biological evaluation of medical devices - Part 23: Tests for irritation | 110 年度新增採認標準 |
| 103 | Cardiovascular 心臟血管醫學 | TFDA-00314 | ISO | ISO 11318:2002 | 2002 | Cardiac Defibrillators - Connector Assembly for Implantable Defibrillators - Dimensional and Test Requirements | 原採認標準 |
| 104 | Cardiovascular 心臟血管醫學 | TFDA-00780 | CNS | CNS 13075 | 2007 | 非侵入式自動血壓計 | 原採認標準 |
| 105 | Cardiovascular | TFDA-00781 | CNS | CNS 15041-1 | 2007 | 非侵入式血壓計－第 1 部：一般規定 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | ar 心臟血管 醫學 | | | | | | |
| 106 | Cardiovascular ar 心臟血管 醫學 | TFDA-00782 | CNS | CNS 15041-2 | 2007 | 非侵入式血壓計－第 2 部：機械式血壓計之補充 規定 | 原採認標準 |
| 107 | Cardiovascular ar 心臟血管 醫學 | TFDA-00783 | CNS | CNS 15041-3 | 2007 | 非侵入式血壓計－第 3 部：機電式血壓量測系統 的補充規定 | 原採認標準 |
| 108 | Cardiovascular ar 心臟血管 醫學 | TFDA-00975 | OIML | OIML R16-2:2002 | 2002 | Non-invasive automated sphygmomanometers | 原採認標準 |
| 109 | Cardiovascular ar 心臟血管 醫學 | TFDA-00978 | CEN | EN 1060-4:2004 | 2004 | Non-invasive sphygmomanometers—Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers | 原採認標準 |
| 110 | Cardiovascular ar 心臟血管 醫學 | TFDA-01179 | AAMI | AAMI EC53:2013(R202 0) | 2020 | ECG trunk cables and patient leadwires | 原採認標準 |
| 111 | Cardiovascular ar 心臟血管 醫學 | TFDA-01180 | AAMI | ANSI/AAMI EC57:2012 (R2020) | 2020 | Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms | 原採認標準 |
| 112 | Cardiovascular ar 心臟血管 醫學 | TFDA-01181 | AAMI | AAMI/IEC 60601-2-4:2010/ A1:2018 | 2018 | Medical electrical equipment - Part 2-4: Particular requirements for basic safety and essential performance of cardiac defibrillators | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 113 | Cardiovascular 心臟血管醫學 | TFDA-01198 | CEN | EN ISO 81060-1:2012 | 2012 | Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type - CORR: July 31, 2012 | 原採認標準 |
| 114 | Cardiovascular 心臟血管醫學 | TFDA-01200 | ISO | ISO 5841-2:2014 | 2014 | Implants for Surgery - Cardiac Pacemakers - Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads - Third Edition | 原採認標準 |
| 115 | Cardiovascular 心臟血管醫學 | TFDA-01203 | IEC | IEC 60601-2-34:2011 ed3.0 | 2011 | Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment | 原採認標準 |
| 116 | Cardiovascular 心臟血管醫學 | TFDA-01205 | IEC | IEC 60601-2-47:2012 ed2.0 | 2012 | Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems | 原採認標準 |
| 117 | Cardiovascular 心臟血管醫學 | TFDA-01208 | ISO | ISO 10555-4:2013 | 2013 | Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters - Second Edition | 原採認標準 |
| 118 | Cardiovascular 心臟血管醫學 | TFDA-01210 | ISO | ISO 17475:2005/COR 1:2006 | 2005 | Corrosion of metals and alloys -- Electrochemical test methods -- Guidelines for conducting potentiostatic and potentiodynamic polarization measurements | 原採認標準 |
| 119 | Cardiovascular 心臟血管醫學 | TFDA-01211 | ISO | ISO 2248:1985 | 1985 | Packaging -- Complete, filled transport packages -- Vertical impact test by dropping | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 120 | Cardiovascular 心臟血管醫學 | TFDA-01213 | ISO | ISO 25539-2:2020 | 2020 | Cardiovascular implants — Endovascular devices — Part 2: Vascular stents | 原採認標準 |
| 121 | Cardiovascular 心臟血管醫學 | TFDA-01214 | ISO | ISO 25539-3:2011 | 2011 | Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters | 原採認標準 |
| 122 | Cardiovascular 心臟血管醫學 | TFDA-01215 | ISO | ISO 5841-3:2013 | 2013 | Implants for surgery -- Cardiac pacemakers -- Part 3: Low-profile connectors (IS-1) for implantable pacemakers | 原採認標準 |
| 123 | Cardiovascular 心臟血管醫學 | TFDA-01218 | ISO | ISO 81060-1:2007 | 2007 | Non-invasive sphygmomanometers - Part 1: Requirements and test methods for nonautomated measurement type. | 原採認標準 |
| 124 | Cardiovascular 心臟血管醫學 | TFDA-01220 | ISO | ISO 8318:2000 | 2000 | Packaging - Complete, Filled Transport Packages and Unit Loads - Sinusoidal Vibration Tests Using a Variable Frequency - Second Edition | 原採認標準 |
| 125 | Cardiovascular 心臟血管醫學 | TFDA-01478 | ASTM | ASTM F2082/F2082M-16 | 2016 | Standard Test Method for Determination of Transformation Temperature of Nickel- Titanium Shape Memory Alloys by Bend and Free Recovery | 原採認標準 |
| 126 | Cardiovascular 心臟血管醫學 | TFDA-01481 | ASTM | ASTM F3036-13 | 2013 | Standard Guide for Testing Absorbable Stents | 原採認標準 |
| 127 | Cardiovascular 心臟血管醫學 | TFDA-01482 | IEC | IEC 60601-2-27:2011 | 2011 | Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 128 | Cardiovascular 心臟血管醫學 | TFDA-01485 | ISO | ISO 15676:2016 | 2016 | Cardiovascular implants and artificial organs - Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) | 原採認標準 |
| 129 | Cardiovascular 心臟血管醫學 | TFDA-01486 | ISO | ISO 25539-1:2017 | 2017 | Cardiovascular implants— Endovascular devices—Part 1: Endovascular prostheses | 原採認標準 |
| 130 | Cardiovascular 心臟血管醫學 | TFDA-01487 | ISO | ISO 5840-1:2021 | 2021 | Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements | 原採認標準 |
| 131 | Cardiovascular 心臟血管醫學 | TFDA-01488 | ISO | ISO 5840-2:2021 | 2021 | Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes | 原採認標準 |
| 132 | Cardiovascular 心臟血管醫學 | TFDA-01489 | ISO | ISO 5840-3:2021 | 2021 | Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques | 原採認標準 |
| 133 | Cardiovascular 心臟血管醫學 | TFDA-01490 | ISO | ISO 7198:2016 | 2016 | Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches | 原採認標準 |
| 134 | Cardiovascular 心臟血管醫學 | TFDA-01492 | ISO | ISO 12417-1:2015 | 2015 | Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements | 原採認標準 |
| 135 | Cardiovascular | TFDA-01783 | ASTM | ASTM F2004-17 | 2017 | Standard Test Method for Transformation | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | ar 心臟血管 醫學 | | | | | Temperature of Nickel-Titanium Alloys by Thermal Analysis | |
| 136 | Cardiovascular ar 心臟血管 醫學 | TFDA-01784 | IEC | IEC 60601-2-4:2010+ AMD1:2018 | 2018 | Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators | 原採認標準 |
| 137 | Cardiovascular ar 心臟血管 醫學 | TFDA-01785 | IEC | IEC 80601-2-30:2018 | 2018 | Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers | 原採認標準 |
| 138 | Cardiovascular ar 心臟血管 醫學 | TFDA-01786 | IEC | IEC 80601-2-49:2018 | 2018 | Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors | 原採認標準 |
| 139 | Cardiovascular ar 心臟血管 醫學 | TFDA-01787 | ISO | ISO 11070 :2014+A1: 2018 | 2014 | Sterile single-use intravascular introducers, dilators and guidewires | 原採認標準 |
| 140 | Cardiovascular ar 心臟血管 醫學 | TFDA-01788 | ISO | ISO 80601-2-61:2017 | 2017 | Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment | 原採認標準 |
| 141 | Cardiovascular ar 心臟血管 醫學 | TFDA-01876 | AAMI | ANSI/AAMI EC12:2000 (R2020) | 2020 | Disposable ECG electrodes | 原採認標準 |
| 142 | Cardiovascular ar 心臟血管 醫學 | TFDA-01877 | AAMI | IEC 60601-2-25:2011(R2016) | 2016 | Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs. | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 143 | Cardiovascular 心臟血管醫學 | TFDA-01878 | ASTM | ASTM F2081 - 06(2017) | 2017 | Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents | 原採認標準 |
| 144 | Cardiovascular 心臟血管醫學 | TFDA-01879 | ASTM | ASTM F1984 - 99(2018) | 2018 | Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials | 原採認標準 |
| 145 | Cardiovascular 心臟血管醫學 | TFDA-01880 | ASTM | ASTM F2079 - 09(2017) | 2017 | Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon Expandable Stents | 原採認標準 |
| 146 | Cardiovascular 心臟血管醫學 | TFDA-01881 | ASTM | ASTM F2394 - 07(2017) | 2017 | Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System | 原採認標準 |
| 147 | Cardiovascular 心臟血管醫學 | TFDA-01882 | ASTM | ASTM F746 - 04(2021) | 2021 | Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials | 原採認標準 |
| 148 | Cardiovascular 心臟血管醫學 | TFDA-01946 | ISO | ISO 8637-3:2018 | 2018 | Extracorporeal systems for blood purification - Part 3: Plasmafilters | 原採認標準 |
| 149 | Cardiovascular 心臟血管醫學 | TFDA-01947 | ISO | ISO 81060-2:2018/A MD 1:2020 | 2020 | Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type - Second Edition | 原採認標準 |
| 150 | Cardiovascular 心臟血管醫學 | TFDA-01948 | ASTM | ASTM F3320-18 | 2018 | Standard Guide for Coating Characterization of Drug Coated Balloons | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 151 | Cardiovascular 心臟血管醫學 | TFDA-01949 | ISO | ISO 5910:2018 | 2018 | Cardiovascular implants and extracorporeal systems - Cardiac valve repair devices | 原採認標準 |
| 152 | Cardiovascular 心臟血管醫學 | TFDA-01950 | AAMI | AAMI/ISO 14117:2019 | 2019 | Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices. | 原採認標準 |
| 153 | Cardiovascular 心臟血管醫學 | TFDA-01951 | ASTM | ASTM G71 - 81(2019) | 2019 | Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes | 原採認標準 |
| 154 | Cardiovascular 心臟血管醫學 | TFDA-01952 | IEC | IEC 60601-2-31:2020 | 2020 | Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source | 原採認標準 |
| 155 | Cardiovascular 心臟血管醫學 | TFDA-01953 | ISO | ISO 14708-2:2019 | 2019 | Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac pacemakers | 原採認標準 |
| 156 | Cardiovascular 心臟血管醫學 | TFDA-01954 | ASTM | ASTM F138 - 19 | 2019 | Standard Specification for Wrought 18 Chromium 14 Nickel 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673) | 原採認標準 |
| 157 | Cardiovascular 心臟血管醫學 | TFDA-01955 | ASTM | ASTM F2942 - 19 | 2019 | Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 158 | Cardiovascular 心臟血管醫學 | TFDA-01956 | ISO | ISO 15674:2016/AMD 1:2020 | 2020 | Cardiovascular implants and artificial organs - Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags | 原採認標準 |
| 159 | Cardiovascular 心臟血管醫學 | TFDA-01957 | ISO | ISO 15675:2016/AMD 1:2020 | 2020 | Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters | 原採認標準 |
| 160 | Cardiovascular 心臟血管醫學 | TFDA-01958 | ISO | ISO 7199:2016/AMD 1:2020 | 2020 | Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) | 原採認標準 |
| 161 | Cardiovascular 心臟血管醫學 | TFDA-01959 | ISO | ISO/TS 17137:2019 | 2019 | Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants | 原採認標準 |
| 162 | Cardiovascular 心臟血管醫學 | TFDA-02111 | ASTM | F1830-19 | 2019 | Standard Practice for Collection and Preparation of Blood for Dynamic In Vitro Evaluation of Blood Pumps | 110 年度新增採認標準 |
| 163 | Cardiovascular 心臟血管醫學 | TFDA-02112 | ASTM | F1841-19 | 2019 | Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps | 110 年度新增採認標準 |
| 164 | Cardiovascular 心臟血管醫學 | TFDA-02113 | IEEE | IEEE Std 1708-2019 | 2019 | Standard for Wearable, Cuffless Blood Pressure Measuring Devices [including: Amendment 1 (2019)] | 110 年度新增採認標準 |
| 165 | Cardiovascular 心臟血管醫學 | TFDA-02114 | ISO | ISO/TS 81060-5:2020 | 2020 | Non-invasive sphygmomanometers - Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of | 110 年度新增採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | automated non-invasive sphygmomanometers | |
| 166 | Cardiovascular 心臟血管醫學 | TFDA-02115 | ISO | ISO 14708-5: 2020 | 2020 | Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices | 110 年度新增採認標準 |
| 167 | Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00373 | ANSI | ADA Specification No.27-1993 | 1993 | Resin-Based Filling Materials | 原採認標準 |
| 168 | Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00381 | ISO | ISO 6360-3: 2005 | 2005 | Dentistry -- Number coding system for rotary instruments -- Part 3: Specific characteristics of burs and cutters | 原採認標準 |
| 169 | Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00382 | ISO | ISO 6360-4: 2004 | 2004 | Dentistry -- Number coding system for rotary instruments -- Part 4: Specific characteristics of diamond instruments | 原採認標準 |
| 170 | Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00383 | ISO | ISO 6360-6: 2004 | 2004 | Dentistry -- Number coding system for rotary instruments -- Part 6: Specific characteristics of abrasive instruments | 原採認標準 |
| 171 | Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00384 | ISO | ISO 6360-7: 2006 | 2006 | Dentistry – Number coding system for rotary instruments – Part 7: Specific characteristics of mandrels and special instruments | 原採認標準 |
| 172 | Dental/ENT 牙科學/耳鼻喉科學 | TFDA-00385 | ISO | ISO 13397-1:1995 | 1995 | Periodontal curettes, dental scalers and excavators -- Part 1: General requirements | 原採認標準 |
| 173 | Dental/ENT 牙科學/耳鼻喉 | TFDA-00387 | ISO | ISO 13397-3:1996 | 1996 | Periodontal curettes, dental scalers and excavators -- Part 3: Dental scalers -- H-type | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 喉科學 | | | | | | |
| 174 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-00388 | ISO | ISO 13397-4:1997 | 1997 | Periodontal curettes, dental scalers and excavators -- Part 4: Dental excavators -- Discoid-type | 原採認標準 |
| 175 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-00389 | ISO | ISO 15854:2021 | 2021 | Dentistry – Casting and baseplate waxes | 原採認標準 |
| 176 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-00687 | ISO | ISO 6877:2006 | 2006 | Dentistry -- Root-canal obturating points | 原採認標準 |
| 177 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-00690 | ISO | ISO 9917-1:2007 | 2007 | Dentistry -- Water-based cements -- Part 1: Powder/liquid acid-base cements | 原採認標準 |
| 178 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-00873 | ISO | ISO 9168:2009 | 2009 | Dentistry -- Hose connectors for air driven dental handpieces | 原採認標準 |
| 179 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01223 | CEN | EN 1639:2009 | 2009 | Dentistry. Medical devices for dentistry. Instruments | 原採認標準 |
| 180 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01224 | CEN | EN 1640:2009 | 2009 | Dentistry. Medical devices for dentistry. Equipment | 原採認標準 |
| 181 | Dental/ENT 牙科學/耳鼻 | TFDA-01225 | CEN | EN 1641:2009 | 2009 | Dentistry. Medical devices for dentistry. Materials | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 喉科學 | | | | | | |
| 182 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01226 | CEN | EN 1642:2011 | 2011 | Dentistry. Medical devices for dentistry. Dental implants | 原採認標準 |
| 183 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01229 | ISO | ISO 13397-2:2005/A md1:2012 | 2012 | Dentistry – Periodontal curettes, dental scalers and excavators – Part 2:Periodontal curettes of Gr-type | 原採認標準 |
| 184 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01232 | ISO | ISO 21563:2013 | 2013 | Dentistry - Hydrocolloid impression materials - First Edition | 原採認標準 |
| 185 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01233 | ISO | ISO 3107:2011 | 2011 | Dentistry — Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements - Fourth Edition | 原採認標準 |
| 186 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01234 | ISO | ISO 6360-2:2004/Am d 1:2011 | 2011 | Dentistry — Number coding system for rotary instruments — Part 2: Shapes AMENDMENT 1 - Second Edition | 原採認標準 |
| 187 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01235 | ISO | ISO 6876:2012 | 2012 | Dentistry - Root canal sealing materials - Third Edition | 原採認標準 |
| 188 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01238 | ADA | ANSI/ADA 96-2012 | 2012 | ANSI/ADA Standard No. 96—Dental Water-based Cements: 2012 | 原採認標準 |
| 189 | Dental/ENT 牙科學/耳鼻 | TFDA-01494 | AAMI | AAMI CI86:2017 | 2017 | Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 喉科學 | | | | | reporting | |
| 190 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01497 | ISO | ISO 10139-2:2016 | 2016 | Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use | 原採認標準 |
| 191 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01498 | ISO | ISO 14801:2016 | 2016 | Dentistry - Implants - Dynamic loading test for endosseous dental implants | 原採認標準 |
| 192 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01499 | ISO | ISO 22674:2016 | 2016 | Dentistry -- Metallic materials for fixed and removable restorations and appliances | 原採認標準 |
| 193 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01500 | ISO | ISO 6360-1:2004/Cor 1:2007 | 2007 | Dentistry — Number coding system for rotary instruments — Part 1: General characteristics | 原採認標準 |
| 194 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01502 | ISO | ISO 6874:2015 | 2015 | Dentistry — Polymer-based pit and fissure sealants | 原採認標準 |
| 195 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01504 | ISO | ISO 7494-2:201 5 | 2015 | Dentistry - Dental units - Part 2: Air, water, suction and wastewater systems - Second Edition | 原採認標準 |
| 196 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01789 | ISO | ISO 10139-1:2018 | 2018 | Dentistry - Soft lining materials for removable dentures - Part 1:Materials for short-term use | 原採認標準 |
| 197 | Dental/ENT 牙科學/耳鼻 | TFDA-01790 | ISO | ISO 10477:2020 | 2020 | Dentistry -- Polymer-based crown and bridge materials | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 喉科學 | | | | | | |
| 198 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01791 | ISO | ISO 11137-3:2017 | 2017 | Sterilization of health care products —Radiation —Part 3:Guidance on dosimetric aspects | 原採認標準 |
| 199 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01792 | ISO | ISO 14457:2017 | 2017 | Dentistry -- Handpieces and motors | 原採認標準 |
| 200 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01793 | ISO | ISO 22112:2017 | 2017 | Dentistry - Artificial teeth for dental prostheses | 原採認標準 |
| 201 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01794 | ISO | ISO 7491:2000 | 2000 | Dental materials—Determination of colour stability | 原採認標準 |
| 202 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01795 | ISO | ISO 7494-1:2018 | 2018 | Dentistry -- Dental units -- Part 1: General requirements and test methods | 原採認標準 |
| 203 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01796 | ISO | ISO 9917-2:2017 | 2017 | Dentistry - Water-based cements - Part 2: Resin-modified cements | 原採認標準 |
| 204 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01883 | ASA | ASA S3.6-2018 | 2018 | American National Standard Specification for Audiometers | 原採認標準 |
| 205 | Dental/ENT 牙科學/耳鼻 | TFDA-01884 | ISO | ISO 6872:2015/AMD | 2018 | Dentistry - Ceramic materials | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 喉科學 | | | 1:2018 | | | |
| 206 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01960 | ISO | ISO 9693:2019 | 2019 | Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems | 原採認標準 |
| 207 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01961 | ASTM | ASTM F1088-18 | 2018 | Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation | 原採認標準 |
| 208 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01962 | ISO | ISO 7405:2018 | 2018 | Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry | 原採認標準 |
| 209 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01963 | ISO | ISO 17730:2020 | 2020 | Dentistry - Fluoride varnishes | 原採認標準 |
| 210 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01964 | ISO | ISO 4049:2019 | 2019 | Dentistry -- Polymer-based restorative materials | 原採認標準 |
| 211 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01965 | IEC | IEC 80601-2-60:2019 | 2019 | Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment | 原採認標準 |
| 212 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-01966 | ASA | ASA S3.22-2014 (R2020) | 2020 | Specification of Hearing Aid Characteristics | 原採認標準 |
| 213 | Dental/ENT 牙科學/耳鼻 | TFDA-01967 | IEC | IEC 60601-2-66:2019 | 2019 | Medical electrical equipment Part 2-66: Particular requirements for the basic safety and essential | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 喉科學 | | | | | performance of hearing instruments and hearing instrument system | |
| 214 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-02116 | ISO | ISO/TR 22442-4:2010 | 2010 | Medical devices utilizing animal tissues and their derivatives — Part 4: Principles for elimination and/or inactivation of transmissible spongiform encephalopathy22agents and validation assays for those processes | 110 年度新增 採認標準 |
| 215 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-02117 | ISO | ISO 10650 Second edition 2018-08 | 2018 | Dentistry — Powered polymerization activators | 110 年度新增 採認標準 |
| 216 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-02118 | ANSI ASA | ANSI ASA S3.7-2016 (Reaffirmed 2020) | 2020 | American National Standard Method for Coupler Calibration of Earphones | 110 年度新增 採認標準 |
| 217 | Dental/ENT 牙科學/耳鼻 喉科學 | TFDA-02119 | ISO | ISO 10271 Third edition 2020-08 | 2020 | Dentistry - Corrosion test methods for metallic materials | 110 年度新增 採認標準 |
| 218 | General I (QS/RM) 通 用(品質管理 系統/風險管 理) | TFDA-00088 | ISO | ISO 10012:2003 | 2003 | Quality assurance requirements for measuring equipment Part 1: Metrological confirmation system for measuring equipment | 原採認標準 |
| 219 | General I (QS/RM) 通 | TFDA-00439 | CNS | CNS14991 | 2006 | 命名—用於醫療器材法規管理資料交換之命名系統的規格 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 用(品質管理系統/風險管理) | | | | | | |
| 220 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00440 | CNS | CNS14989 | 2006 | 醫療器材風險管理 | 原採認標準 |
| 221 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-00441 | CNS | CNS14990 | 2006 | 醫療器材—用於醫療器材標識、標示與資訊之符號 | 原採認標準 |
| 222 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01013 | ISO | ISO 14155:2020 | 2020 | Clinical investigation of medical devices for human subjects -- Good clinical practice | 原採認標準 |
| 223 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01505 | AAMI | AAMI TIR69:2017(R2020) | 2020 | Risk management of radio-frequency wireless coexistence for medical devices and systems | 原採認標準 |
| 224 | General I | TFDA-01507 | EN | EN 45502-1:2015 | 2015 | Implants for surgery - Active implantable medical | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | (QS/RM) 通用(品質管理系統/風險管理) | | | | | devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer | |
| 225 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01509 | IEC | IEC TR 80002-1:2009 | 2009 | Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software | 原採認標準 |
| 226 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01510 | ISO | ISO 13485:2016 | 2016 | Medical devices — Quality management systems — Requirements for regulatory purposes | 原採認標準 |
| 227 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01511 | ISO | ISO 15223-1:2016 | 2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements | 原採認標準 |
| 228 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01512 | ISO | ISO 16061:2021 | 2021 | Instruments for use in association with non-active surgical implants — General requirements | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 229 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01513 | ISO | ISO 16142-1:2016 | 2016 | Medical devices-Recognized essential principles of safety and performance of medical devices-Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards | 原採認標準 |
| 230 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01514 | ISO | ISO 16142-2:2017 | 2017 | Medical devices - recognized essential principles of safety and performance of medical devices - part 2: general ESSENTIAL PRINCIPLES AND ADDITIONAL SPECIFIC ESSENTIAL PRINCIPLES FOR ALL IVD MEDICAL DEVICES AND GUIDANCE ON THE SELECTION OF STANDARDS | 原採認標準 |
| 231 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01517 | ISO | ISO 80369-6:2016 | 2016 | Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications | 原採認標準 |
| 232 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01885 | AAMI | AAMI HE75:2009(R2018) | 2018 | Human factors engineering - Design of medical devices | 原採認標準 |
| 233 | General I (QS/RM) 通 | TFDA-01886 | ISO | IEC 80369-5:2016/CO | 2017 | Small-bore connectors for liquids and gases in healthcare applications—Part 5: Connectors for | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 用(品質管理系統/風險管理) | | | R 1:2017 | | limb cuff inflation applications | |
| 234 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01968 | ISO | ISO 14971:2019 | 2019 | Medical devices -- Application of risk management to medical devices | 原採認標準 |
| 235 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01969 | ISO | ISO/TR 24971:2020 | 2020 | Medical devices — Guidance on the application of ISO 14971 | 原採認標準 |
| 236 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01970 | IEC | IEC 62366-1:2015+A MD1:2020 | 2020 | Medical devices –Part 1: Application of usability engineering to medical devices | 原採認標準 |
| 237 | General I (QS/RM) 通用(品質管理系統/風險管理) | TFDA-01971 | ISO | ISO 80369-3:2016/A MD 1:2019 | 2019 | Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications | 原採認標準 |
| 238 | General I | TFDA-02120 | ISO | ISO 7010 Third | 2019 | Graphical symbols - Safety colours and safety signs | 110 年度新增 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | (QS/RM) 通用(品質管理系統/風險管理) | | | edition 2019-07 | | - Registered safety signs | 採認標準 |
| 239 | General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00126 | ISO | ISO 8536-5:2004 | 2004 | Infusion Equipment for Medical Use - Part 5: Burette Type Infusion Sets | 原採認標準 |
| 240 | General Plastic Surgery/General Hospital 一般及整形外科手術/一般醫院及個人使用裝置 | TFDA-00298 | CNS | CNS 14775 | 2003 | 醫用面罩材料細菌過濾效率試驗法—使用金黃色葡萄球菌生物氣霧 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus | 原採認標準 |
| 241 | General Plastic Surgery/General Hospital | TFDA-00463 | ISO | ISO 11608-4:2006 | 2006 | Pen-injectors for medical use – Part 4: Requirements and test methods for electronic and electromechanical pen-injectors | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 242 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00464 | ISO | ISO 21649:2006 | 2006 | Needle-free injectors for medical use –Requirements and test methods | 原採認標準 |
| 243 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00467 | ISO | ISO 8362-3:2001 | 2001 | Injection containers and accessories -- Part 3: Aluminium caps for injection vials | 原採認標準 |
| 244 | General Plastic Surgery/General Hospital | TFDA-00471 | ISO | ISO 8362-7:2006 | 2006 | Injection containers and accessories –Part 7: Injection caps made of aluminiumplastics combinations without overlapping plastics part | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 245 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00478 | CNS | CNS 4397 | 1999 | 脫脂紗布 | 原採認標準 |
| 246 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00589 | CNS | CNS 15036-1 | 2006 | 用於人類血液和血液成品塑膠可折疊之容器— 第 1 部：慣用容器（血袋） | 原採認標準 |
| 247 | General Plastic Surgery/General Hospital | TFDA-00590 | CNS | CNS 13460 | 1994 | 電刀裝置 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 248 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00592 | CNS | CNS 14624-2 | 2002 | 醫療用輸液設備—第二部份：點滴瓶瓶塞 | 原採認標準 |
| 249 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00593 | CNS | CNS 14624-3 | 2002 | 醫療用輸液設備—第三部份：點滴瓶鋁蓋 | 原採認標準 |
| 250 | General Plastic Surgery/General Hospital | TFDA-00599 | ISO | ISO 15883-2:2006 | 2006 | Washer-disinfectors -- Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | glassware, etc. | |
| 251 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00600 | ISO | ISO 15883-3:2006 | 2006 | Washer-disinfectors -- Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers | 原採認標準 |
| 252 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00601 | ISO | ISO 15883-5:2021 | 2021 | Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy | 原採認標準 |
| 253 | General Plastic Surgery/General Hospital | TFDA-00784 | CNS | CNS 15042 | 2007 | 間歇性測定患者體溫之紅外線體溫計 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 254 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00785 | CNS | CNS 15043 | 2007 | 間歇性測定患者體溫之電子式體溫計 | 原採認標準 |
| 255 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00786 | CNS | CNS 15044 | 2007 | 體溫計探針護套 | 原採認標準 |
| 256 | General Plastic Surgery/General Hospital | TFDA-00787 | CNS | CNS 15212-3 | 2008 | 電子體溫計—第 3 部：具最大值（非預測性與預測性）裝置之小型電子體溫計的性能 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 257 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00788 | CNS | CNS 15212-4 | 2008 | 電子體溫計－第 4 部：用於連續量測之電子體溫計的性能 | 原採認標準 |
| 258 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00789 | CNS | CNS 15212-5 | 2008 | 電子體溫計－第 5 部：紅外線耳溫計（具最大值裝置）的性能 | 原採認標準 |
| 259 | General Plastic Surgery/General Hospital | TFDA-00790 | CNS | CNS 15226 | 2009 | 單次使用之無菌橡膠手套－規格 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 260 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00791 | CNS | CNS 15227 | 2009 | 單次使用之醫用檢驗手套－第 1 部：以乳膠或橡 膠溶液製成之手套規格 | 原採認標準 |
| 261 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00917 | ISO | ISO 8536-2:2010 | 2010 | Infusion equipment for medical use -- Part 2: Closures for infusion bottles | 原採認標準 |
| 262 | General Plastic Surgery/General Hospital | TFDA-00918 | ISO | ISO 8536-3:2009/AWI AMD 1 | 2009 | Infusion equipment for medical use -- Part 3: Aluminium caps for infusion bottles | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 263 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00920 | ISO | ISO 8536-7:2009 | 2009 | Infusion equipment for medical use -- Part 7: Caps made of aluminium-plastics combinations for infusion bottles | 原採認標準 |
| 264 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-00928 | ISO | ISO 8362-6:2010 | 2016 | Injection containers and accessories -- Part 6: Caps made of aluminium-plastics combinations for injection vials | 原採認標準 |
| 265 | General Plastic Surgery/General Hospital | TFDA-00988 | OIML | OIML R115:1995 | 1995 | Clinical electrical thermometers with maximum device | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 266 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01259 | AAMI | AAMI PB70:2012 | 2012 | Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities | 原採認標準 |
| 267 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01272 | ASTM | ASTM F1671/F1671M-1 3 | 2013 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System | 原採認標準 |
| 268 | General Plastic Surgery/General Hospital | TFDA-01275 | ASTM | ASTM F2119-07(2013) | 2013 | Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 269 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01276 | ASTM | ASTM F2172-02/(R)201 1 | 2011 | Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers | 原採認標準 |
| 270 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01281 | ASTM | ASTM F86 - 21 | 2021 | Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants | 原採認標準 |
| 271 | General Plastic Surgery/General Hospital | TFDA-01283 | CEN | EN 13726-1:2002 | 2002 | Test methods for primary wound dressings - Part 1: Aspects of absorbency | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 272 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01287 | CNS | CNS 14755 | 2011 | 拋棄式防塵口罩 (Disposable dust respirators) | 原採認標準 |
| 273 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01288 | CNS | CNS 14778 | 2003 | 防護衣詞彙 (Terminology relating to protective clothing) (IDE ASTM F1494-01) | 原採認標準 |
| 274 | General Plastic Surgery/General Hospital | TFDA-01289 | CNS | CNS 14798 | 2004 | 拋棄式醫用防護衣—性能要求(The performance requirements for disposable medical protective clothing) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 275 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01290 | CNS | CNS 14799 | 2004 | 防護衣材料對合成血液穿透阻力試驗法 (Method of test for resistance of materials used in protective clothing to penetration by synthetic blood) (IDE ASTM F1670-98) | 原採認標準 |
| 276 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01291 | CNS | CNS 14800 | 2004 | 使用 Phi-X174 噬菌體穿透力之試驗系統供防護衣材料對血液媒介病原穿透阻力的試驗法 (Method of test for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system) (IDE AATCC 42-2000) | 原採認標準 |
| 277 | General Plastic Surgery/General Hospital | TFDA-01292 | CNS | CNS 14801 | 2004 | 防護衣材料防水性試驗法－衝擊穿透試驗 (Method of test for water resistance of material used in protective clothing (Impact penetration test)) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 278 | General Plastic Surgery/Gene ral Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01293 | CNS | CNS 15554 | 2012 | 醫電設備電性安全－第 2-52 部：醫護床基本安全 及必要性能的特殊要求 (Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds) (IDE IEC 60601-2-52:2010) | 原採認標準 |
| 279 | General Plastic Surgery/Gene ral Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01294 | IEC | IEC 60601-2-24:2012 | 2012 | Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers | 原採認標準 |
| 280 | General Plastic Surgery/Gene ral Hospital | TFDA-01295 | IEC | IEC 60601-2-41:2009 +AMD1:2013 | 2013 | Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis - Edition 2.1 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 281 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01301 | ISO | ISO 10555-3:2013 | 2013 | Intravascular catheters -- Sterile and single-use catheters -- Part 3: Central venous catheters | 原採認標準 |
| 282 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01302 | ISO | ISO 10555-5:2013 | 2013 | Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters | 原採認標準 |
| 283 | General Plastic Surgery/General Hospital | TFDA-01305 | ISO | ISO 11608-2:2012 | 2012 | Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 284 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01306 | ISO | ISO 11608-3:2012 | 2012 | Needle-based injection systems for medical use -- Requirements and test methods -- Part 3: Finished containers | 原採認標準 |
| 285 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01307 | ISO | ISO 7740:1985 | 1985 | Instruments for surgery, scalpels with detachable blades, fitting dimensions | 原採認標準 |
| 286 | General Plastic Surgery/General Hospital | TFDA-01309 | ISO | ISO 8362-4:2011 | 2011 | Injection containers and accessories -- Part 4: Injection vials made of moulded glass | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 287 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01310 | ISO | ISO 8536-1:2011 | 2011 | Infusion equipment for medical use — Part 1: Infusion glass bottles - Fourth Edition | 原採認標準 |
| 288 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01312 | ISO | ISO 9187-1:2010 | 2010 | Injection equipment for medical use -- Part 1: Ampoules for injectables | 原採認標準 |
| 289 | General Plastic Surgery/General Hospital | TFDA-01320 | ISO | ISO 10282:2014 | 2014 | Single-use sterile rubber surgical gloves - Specification - Third Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 290 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01520 | ASTM | ASTM D7160-16 | 2016 | Standard Practice for Determination of Expiration Dating for Medical Gloves | 原採認標準 |
| 291 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01521 | ASTM | ASTM D7161-16 | 2016 | Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions | 原採認標準 |
| 292 | General Plastic Surgery/General Hospital | TFDA-01523 | ASTM | ASTM F2051-00/(R)201 4 | 2014 | Standard Specification for Implantable Saline Filled Breast Prosthesis | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 293 | General Plastic Surgery/Gene ral Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01528 | EN | EN 1865-1:2010+A1: 2015 | 2015 | Patient handling equipment used in road ambulances Part 1: General stretcher systems and patient handling equipmen | 原採認標準 |
| 294 | General Plastic Surgery/Gene ral Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01529 | EN | EN 1865-2:2010+A1: 2015 | 2015 | Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher | 原採認標準 |
| 295 | General Plastic Surgery/Gene ral Hospital | TFDA-01530 | EN | EN 1865-3:2012+A1: 2015 | 2015 | Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 296 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01531 | EN | EN 455-2:2015 | 2015 | Medical gloves for single use. Requirements and testing for physical properties | 原採認標準 |
| 297 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01532 | EN | EN 455-3:2015 | 2015 | Medical gloves for single use. Requirements and testing for biological evaluation | 原採認標準 |
| 298 | General Plastic Surgery/General Hospital | TFDA-01534 | IEC | IEC 60601-2-20:2020 | 2020 | Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 299 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01535 | IEC | IEC 60601-2-21:2020 | 2020 | Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers | 原採認標準 |
| 300 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01536 | IEC | IEC 60601-2-46:2016 | 2016 | Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables | 原採認標準 |
| 301 | General Plastic Surgery/General Hospital | TFDA-01537 | IEC | IEC 60601-2-50:2020 | 2020 | Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 302 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01538 | IEC | IEC 60601-2-52:2009 +AMD1:2015 | 2015 | Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds | 原採認標準 |
| 303 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01539 | IEC | IEC 60601-2-35:2020 | 2020 | 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 |
| 304 | General Plastic Surgery/General Hospital | TFDA-01542 | ISO | ISO 1135-4:2015 | 2015 | Transfusion equipment for medical use Part 4: Transfusion sets for single use, gravity feed | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 305 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01543 | ISO | ISO 11608-5:2012 | 2012 | Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions | 原採認標準 |
| 306 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01544 | ISO | ISO 15883-1:2006/A md1:2014 | 2014 | Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests | 原採認標準 |
| 307 | General Plastic Surgery/General Hospital | TFDA-01545 | ISO | ISO 3826-4 :2015 | 2015 | Plastics collapsible containers for human blood and blood components Part 4: Aphaeresis blood bag systems with integrated features | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 308 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01546 | ISO | ISO 6009:2016 | 2016 | Hypodermic needles for single use - Colour coding for identification | 原採認標準 |
| 309 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01547 | ISO | ISO 7864:2016 | 2016 | Sterile hypodermic needles for single use — Requirements and test methods | 原採認標準 |
| 310 | General Plastic Surgery/General Hospital | TFDA-01548 | ISO | ISO 80369-20:2015 | 2015 | Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 311 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01551 | ISO | ISO 8362-2:2015 | 2015 | Injection containers and accessories - Part 2: Closures for injection vials | 原採認標準 |
| 312 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01552 | ISO | ISO 8362-5:2016 | 2016 | Injection containers and accessories - Part 5: Freeze drying closures for injection vials | 原採認標準 |
| 313 | General Plastic Surgery/General Hospital | TFDA-01553 | ISO | ISO 8536-10:2015 | 2015 | Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment (ISO 8536-10:2015) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 314 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01554 | ISO | ISO 8536-11:2015 | 2015 | Infusion equipment for medical use - Part 11: Infusion filters for single use with pressure infusion equipment (ISO 8536-11:2015) | 原採認標準 |
| 315 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01555 | ISO | ISO 8536-6:2016 | 2016 | Infusion equipment for medical use - Part 6: Freeze drying closures for infusion bottles | 原採認標準 |
| 316 | General Plastic Surgery/General Hospital | TFDA-01556 | ISO | ISO 8536-8:2015 | 2015 | Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus (ISO 8536-8:2015) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 317 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01557 | ISO | ISO 8536-9:2015 | 2015 | Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment (ISO 8536-9:2015) | 原採認標準 |
| 318 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01558 | ISO | ISO 8537:2016 | 2016 | Sterile single-use syringes, with or without needle, for insulin | 原採認標準 |
| 319 | General Plastic Surgery/General Hospital | TFDA-01559 | ISO | ISO 9626:2016 | 2016 | Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 320 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01799 | ASTM | ASTM F703-18 | 2018 | Standard Specification for Implantable Breast Prostheses | 原採認標準 |
| 321 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01800 | CNS | CNS 14774 | 2018 | 醫用面(口)罩 | 原採認標準 |
| 322 | General Plastic Surgery/General Hospital | TFDA-01801 | IEC | IEC 60601-2-19:2020 | 2020 | Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 323 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01802 | IEC | IEC 80601-2-59:2017 | 2017 | Medical electrical equipment -- Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening | 原採認標準 |
| 324 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01803 | ISO | ISO 10555-1:2013/A MD 1:2017 | 2017 | Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements | 原採認標準 |
| 325 | General Plastic Surgery/General Hospital | TFDA-01804 | ISO | ISO 7886-1:2017 | 2017 | Sterile Hypodermic Syringes for Single Use - Part 1: Syringes for Manual Use | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 326 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01875 | ISO | ISO 21171:2006 | 2006 | Medical gloves Determination of removable surface powder | 原採認標準 |
| 327 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01887 | ASTM | ASTM F881 - 94(2014) | 2014 | Standard Specification for Silicone Elastomer Facial Implants | 原採認標準 |
| 328 | General Plastic Surgery/General Hospital | TFDA-01888 | ASTM | ASTM F1441 - 03(2014) | 2014 | Standard Specification for Soft-Tissue Expander Devices | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 329 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01889 | ASTM | ASTM F754 - 08(2015) | 2015 | Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders | 原採認標準 |
| 330 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01890 | ASTM | ASTM E1104 - 98(2016) | 2016 | Standard Specification for Clinical Thermometer Probe Covers and Sheaths | 原採認標準 |
| 331 | General Plastic Surgery/General Hospital | TFDA-01891 | ASTM | ASTM E1965 - 98(2016) | 2016 | Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 332 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01892 | AAMI | AAMI BP22:1994/(R201 6) | 2016 | Blood pressure transducers | 原採認標準 |
| 333 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01893 | ASTM | ASTM D6124 - 06(2017) | 2017 | Standard Test Method for Residual Powder on Medical Gloves | 原採認標準 |
| 334 | General Plastic Surgery/General Hospital | TFDA-01894 | ASTM | ASTM D6355 - 07(2017) | 2017 | Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 335 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01895 | ASTM | ASTM E1112 - 00(2018) | 2018 | Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature | 原採認標準 |
| 336 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01896 | ISO | ISO 80601-2-56:2017/ AMD 1:2018 | 2018 | Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement | 原採認標準 |
| 337 | General Plastic Surgery/General Hospital | TFDA-01897 | ASTM | ASTM F1670 / F1670M - 17a | 2017 | Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 338 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01898 | ISO | ISO 11193-1:2020 | 2020 | Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution | 原採認標準 |
| 339 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01972 | CEN | EN 13795-1:2019 | 2019 | Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns | 原採認標準 |
| 340 | General Plastic Surgery/General Hospital | TFDA-01973 | CEN | EN 13795-2:2019 | 2019 | Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 341 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01974 | ASTM | ASTM F1580-18 | 2018 | Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants | 原採認標準 |
| 342 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01975 | ASTM | ASTM F2213-17 | 2017 | Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment | 原採認標準 |
| 343 | General Plastic Surgery/General Hospital | TFDA-01976 | ASTM | ASTM F75-18 | 2018 | Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 344 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01977 | ASTM | ASTM D6499-18 | 2018 | Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products | 原採認標準 |
| 345 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01978 | ASTM | ASTM D7169 - 20e1 | 2020 | Standard Test Method for Boiling Point Distribution of Samples with Residues Such as Crude Oils and Atmospheric and Vacuum Residues by High Temperature Gas Chromatography | 原採認標準 |
| 346 | General Plastic Surgery/General Hospital | TFDA-01979 | EN | EN 14683:2019 | 2019 | Medical face masks - Requirements and test methods | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 347 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01980 | ISO | ISO 8362-1:2018 | 2018 | Injection containers and accessories - Part 1: Injection vials made of glass tubing | 原採認標準 |
| 348 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01981 | ISO | ISO 7886-2:2020 | 2020 | Sterile Hypodermic Syringes for Single Use - Part 2: Syringes for use with Power-Driven Syringe Pumps | 原採認標準 |
| 349 | General Plastic Surgery/General Hospital | TFDA-01982 | ISO | ISO 7886-3:2020 | 2020 | Sterile hypodermic syringes for single use -- Part 3: Auto-disable syringes for fixed-dose immunization | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 350 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01983 | CEN | EN 455-1:2020 | 2020 | Medical gloves for single use —Part 1: Requirements and testing for freedom from holes | 原採認標準 |
| 351 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01984 | ASTM | ASTM D3577 - 19 | 2019 | Standard Specification for Rubber Surgical Gloves | 原採認標準 |
| 352 | General Plastic Surgery/General Hospital | TFDA-01985 | ASTM | ASTM D3578 - 19 | 2019 | Standard Specification for Rubber Examination Gloves | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 353 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01986 | ASTM | ASTM D5151 - 19 | 2019 | Standard Test Method for Detection of Holes in Medical Gloves | 原採認標準 |
| 354 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01987 | ASTM | ASTM D6978 - 05(2019) | 2019 | Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs | 原採認標準 |
| 355 | General Plastic Surgery/General Hospital | TFDA-01988 | ASTM | ASTM F2182 - 19e2 | 2019 | Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 356 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01989 | ASTM | ASTM F2503 - 20 | 2020 | Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment | 原採認標準 |
| 357 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01990 | ASTM | ASTM F899 - 20 | 2020 | Standard Specification for Wrought Stainless Steels for Surgical Instruments | 原採認標準 |
| 358 | General Plastic Surgery/General Hospital | TFDA-01991 | ISO | ISO 8536-4:2019 | 2019 | Infusion equipment for medical use -- Part 4: Infusion sets for single use, gravity feed | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 359 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01992 | ASTM | ASTM A908 - 03(2019) | 2019 | Standard Specification for Stainless Steel Needle Tubing | 原採認標準 |
| 360 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01993 | ASTM | ASTM D5250 - 19 | 2019 | Standard Specification for Poly(vinyl chloride) Gloves for Medical Application | 原採認標準 |
| 361 | General Plastic Surgery/General Hospital | TFDA-01994 | ASTM | ASTM F2710 - 19 | 2019 | Standard Consumer Safety Performance Specification for Commercial Cribs | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 362 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-01995 | ASTM | ASTM D6319 - 19 | 2019 | Standard Specification for Nitrile Examination Gloves for Medical Application | 原採認標準 |
| 363 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-02121 | ASTM | D6977-19 | 2019 | Standard Specification for Polychloroprene Examination Gloves for Medical Application | 110 年度新增 採認標準 |
| 364 | General Plastic Surgery/General Hospital | TFDA-02122 | ASTM | D7103-19 | 2019 | Standard Guide for Assessment of Medical Gloves | 110 年度新增 採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 365 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-02123 | AAMI | AAMI TIR38:2019 | 2019 | Medical device safety assurance case guidance | 110 年度新增 採認標準 |
| 366 | General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-02124 | EN ISO | 15747:2019 | 2019 | Plastic containers for intravenous injections | 110 年度新增 採認標準 |
| 367 | 6 General Plastic Surgery/General Hospital | TFDA-02125 | ASTM | ASTM F2407-20 | 2020 | Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities | 110 年度新增 採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | | | | | | |
| 368 | 6 General Plastic Surgery/General Hospital 一般及整形 外科手術/ 一般醫院及個 人使用裝置 | TFDA-02126 | ISO | ISO 22610:2018 | 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 | 110 年度新增 採認標準 |
| 369 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00049 | CLSI | NCCLS GP14-A:1996 | 1996 | Labeling of Home-Use In Vitro Testing Products; Approved Guideline | 原採認標準 |
| 370 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00188 | CLSI | H15-A3 | 2000 | Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition | 原採認標準 |
| 371 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00192 | CLSI | M15-A | 2000 | Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 372 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00319 | CEN | EN 13612:2002 | 2002 | Performance evaluation of in vitro diagnostic medical devices | 原採認標準 |
| 373 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00321 | ISO | ISO 18153:2003 | 2003 | In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials | 原採認標準 |
| 374 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00328 | CLSI | H56-A | 2006 | Body fluid analysis for cellular composition | 原採認標準 |
| 375 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00329 | CLSI | I/LA02-A2 | 2006 | Quality assurance of laboratory tests for autoantibodies to nuclear antigens: (1)Indirect fluorescence assay for microscopy and (2) Microtiter enzyme immunoassay methods | 原採認標準 |
| 376 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00334 | CLSI | C39-A | 2000 | A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard | 原採認標準 |
| 377 | In Vitro Diagnostics 體外診斷醫 | TFDA-00336 | CLSI | C44-A | 2002 | Harmonization of Glycohemoglobin Measurements; Approved Guideline | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 378 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00337 | CLSI | C45-A | 2004 | Measurement of Free Thyroid Hormones; - Approved Guideline | 原採認標準 |
| 379 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00339 | CLSI | H45-A2 | 2005 | Performance of the Bleeding Time Test; Approved Guideline | 原採認標準 |
| 380 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00481 | CLSI | POCT01-A2 | 2006 | Point-of-Care Connectivity; Approved Standard- Second Edition | 原採認標準 |
| 381 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00494 | CLSI | C37-A | 1999 | Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline | 原採認標準 |
| 382 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00496 | CLSI | CLSI EP06 Ed2 | 2020 | Evaluation of the Linearity of Quantitative Measurement Procedures | 原採認標準 |
| 383 | In Vitro Diagnostics 體外診斷醫 | TFDA-00506 | CLSI | M26-A | 1999 | Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 384 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00512 | CLSI | MM13-A | 2006 | Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline | 原採認標準 |
| 385 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00646 | CLSI | H21-A5 | 2008 | Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - Fifth Edition | 原採認標準 |
| 386 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00647 | CLSI | I/LA21-A2 | 2008 | Clinical Evaluation of Immunoassays; Approved Guideline-Second Edition | 原採認標準 |
| 387 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00651 | CLSI | H20-A2 | 2007 | Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition | 原採認標準 |
| 388 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00652 | CLSI | H42-A2 | 2007 | Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline - Second Edition | 原採認標準 |
| 389 | In Vitro Diagnostics 體外診斷醫 | TFDA-00653 | CLSI | H43-A2 | 2007 | Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline - Second Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 390 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00654 | CLSI | H44-A2 | 2004 | Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry and Supravital Dyes); Approved Guideline- Second Edition | 原採認標準 |
| 391 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00655 | CLSI | I/LA18-A2 | 2001 | Specifications for Immunological Testing for Infectious Diseases; Approved Guideline - Second Edition | 原採認標準 |
| 392 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00658 | CLSI | M28-A2 | 2005 | Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline - Second Edition | 原採認標準 |
| 393 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00661 | CLSI | EP12-A2 | 2008 | User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition | 原採認標準 |
| 394 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00832 | CLSI | EP18-A2 | 2009 | Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline-Second Edition | 原採認標準 |
| 395 | In Vitro Diagnostics 體外診斷醫 | TFDA-00834 | CLSI | GP16-A3 | 2009 | Urinalysis; Approved Guideline - Third Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 396 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00835 | CLSI | C46-A2 | 2009 | Blood Gas and pH Analysis and Related Measurements; Approved Guideline-Second Edition | 原採認標準 |
| 397 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00839 | CLSI | H26-A2 | 2010 | Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard-Second Edition | 原採認標準 |
| 398 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00840 | CLSI | M22-A3 | 2004 | Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard- Third Edition (2004) | 原採認標準 |
| 399 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00850 | CLSI | MM11-A | 2007 | Molecular Methods for Bacterial Strain Typing; Approved Guideline | 原採認標準 |
| 400 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00851 | CLSI | C43-A2 | 2010 | Gas Chromatography/Mass Spectrometry Confirmation of Drugs; Approved Guideline-Second Edition | 原採認標準 |
| 401 | In Vitro Diagnostics 體外診斷醫 | TFDA-00941 | CLSI | H54-A | 2005 | Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 402 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00942 | CLSI | H57-A | 2008 | Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline | 原採認標準 |
| 403 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00943 | CLSI | I/LA29-A | 2008 | Detection of HLA-Specific Alloantibody by Flow Cytometry and Solid Phase Assays; Approved Guideline | 原採認標準 |
| 404 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-00945 | CLSI | EP25-A | 2009 | Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline | 原採認標準 |
| 405 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01107 | CLSI | C61-A | 1998 | Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard | 原採認標準 |
| 406 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01108 | CLSI | C40-A2 | 2013 | Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine; Approved Guideline | 原採認標準 |
| 407 | In Vitro Diagnostics 體外診斷醫 | TFDA-01109 | CLSI | EP17-A2 | 2012 | Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 408 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01110 | CLSI | GP40-A4-AMD | 2012 | Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline, Fourth Edition | 原採認標準 |
| 409 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01111 | CLSI | GP42-A6 | 2008 | Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard--Sixth Edition | 原採認標準 |
| 410 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01112 | CLSI | M39-A4 | 2014 | Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline - Fourth Edition; Vol. 34; No. 2 | 原採認標準 |
| 411 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01113 | CLSI | MM09-A2 | 2014 | Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline | 原採認標準 |
| 412 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01115 | CLSI | EP10-A3-AMD:2 014(R2019) | 2019 | Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline - Third Edition | 原採認標準 |
| 413 | In Vitro Diagnostics 體外診斷醫 | TFDA-01116 | CLSI | EP24-A2 | 2011 | Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline - | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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|-----|-----------------------------------------|------------|------|-----------|------|------------------------------------------------------------------------------------------------------------------------|-------|
| | 療器材 | | | | | Second Edition | |
| 414 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01117 | CLSI | EP28-A3C | 2010 | Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition | 原採認標準 |
| 415 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01119 | CLSI | GP39-A6 | 2010 | Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition | 原採認標準 |
| 416 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01120 | CLSI | I/LA25-A2 | 2011 | Maternal Serum Screening; Approved Standard, Second Edition | 原採認標準 |
| 417 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01127 | CLSI | MM01-A3 | 2012 | Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline | 原採認標準 |
| 418 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01128 | CLSI | MM05-A2 | 2012 | Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline-Second Edition,MM05A2E | 原採認標準 |
| 419 | In Vitro Diagnostics 體外診斷醫 | TFDA-01129 | CLSI | MM06-A2 | 2010 | Quantitative Molecular Methods for Infectious Diseases; Approved Guideline - Second Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 420 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01130 | CLSI | MM14-A2 | 2013 | Design of Molecular Proficiency Testing/External Quality Assessment; Approved Guideline—Second Edition | 原採認標準 |
| 421 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01131 | CLSI | POCT12-A3 | 2013 | Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline, Third Edition, | 原採認標準 |
| 422 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01133 | CLSI | CLSI POCT14 : 2020 | 2020 | Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline | 原採認標準 |
| 423 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01134 | CLSI | QMS06-A3 | 2011 | Quality Management System: Continual Improvement; Approved Guideline - Third Edition; Vol 31; No 14 | 原採認標準 |
| 424 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01137 | CNS | CNS 15449-2-101 | 2014 | 量測、控制及實驗室使用電氣設備安全規定—第 2-101 部:體外診斷(IVD)醫用設備之個別規定 Safe requirements for electrical for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IDT: IEC 61010-2-101:2002) | 原採認標準 |
| 425 | In Vitro | TFDA-01138 | CLSI | GP34-A | 2010 | Validation and Verfication of Tubes for Venous and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | Diagnosics 體外診斷醫 療器材 | | | | | Capillary Blood Specimen Collection; Approved Guidance | |
| 426 | In Vitro Diagnosics 體外診斷醫 療器材 | TFDA-01139 | EN | EN 13532 | 2012 | General requirements for in vitro diagnostic medical devices for self-testing | 原採認標準 |
| 427 | In Vitro Diagnosics 體外診斷醫 療器材 | TFDA-01143 | IEC | IEC 61326-2-6:2020 | 2020 | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment - Edition 2.0 | 原採認標準 |
| 428 | In Vitro Diagnosics 體外診斷醫 療器材 | TFDA-01144 | ISO | ISO 15193:2009 | 2009 | In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures - Second Edition | 原採認標準 |
| 429 | In Vitro Diagnosics 體外診斷醫 療器材 | TFDA-01145 | ISO | ISO 15194:2009 | 2009 | In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation - Second Edition | 原採認標準 |
| 430 | In Vitro Diagnosics 體外診斷醫 療器材 | TFDA-01146 | ISO | ISO 15197:2013 | 2013 | In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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|-----|-----------------------------------------|------------|------|---------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| 431 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01147 | ISO | ISO 18113-1:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements - First Edition | 原採認標準 |
| 432 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01148 | ISO | ISO 18113-2:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use - First Edition | 原採認標準 |
| 433 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01149 | ISO | ISO 18113-3:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use - First Edition | 原採認標準 |
| 434 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01150 | ISO | ISO 18113-4:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing - First Edition | 原採認標準 |
| 435 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01151 | ISO | ISO 18113-5:2009 | 2009 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing - First Edition | 原採認標準 |
| 436 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01560 | CLSI | AUTO11-A2 | 2014 | Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard - Second Edition; Vol 34; No 17 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 437 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01561 | CLSI | C24 | 2016 | Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions | 原採認標準 |
| 438 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01562 | CLSI | C62-A | 2014 | Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline - Vol 34; No 16 | 原採認標準 |
| 439 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01563 | CLSI | EP05-A3 | 2014 | Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline | 原採認標準 |
| 440 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01564 | CLSI | EP14-A3 | 2014 | Evaluation of Matrix Effects; Approved Guideline | 原採認標準 |
| 441 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01565 | CLSI | EP15-A3:2014(R 2019) | 2019 | User Verification of Performance for Precision and Trueness | 原採認標準 |
| 442 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01566 | CLSI | CLSI EP19 : 2020 | 2020 | A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures - Second Edition; Vol 35; No 10 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 443 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01567 | CLSI | EP21 | 2016 | Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures | 原採認標準 |
| 444 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01568 | CLSI | I/LA20 | 2016 | Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities | 原採認標準 |
| 445 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01571 | CLSI | MM03 | 2015 | Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline | 原採認標準 |
| 446 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01572 | CLSI | MM21 | 2015 | Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications | 原採認標準 |
| 447 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01573 | CLSI | POCT04 | 2016 | Essential Tools for Implementation and Management of a Point-of-Care Testing Program - Third Edition | 原採認標準 |
| 448 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01574 | CLSI | POCT13:2018 | 2018 | Glucose Monitoring in Settings Without Laboratory Support | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 449 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01578 | ISO | ISO 22870:2016 | 2016 | Point-of-care testing (POCT) - Requirements for quality and competence | 原採認標準 |
| 450 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01579 | ISO | ISO 17822:2020 | 2020 | In vitro diagnostic test systems — Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens — Part 1: General requirements, terms and definitions | 原採認標準 |
| 451 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01899 | CLSI | C49 | 2018 | Analysis of Body Fluids in Clinical Chemistry; Approved Guideline | 原採認標準 |
| 452 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01900 | CLSI | EP09c | 2018 | Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition | 原採認標準 |
| 453 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01901 | CLSI | M27 | 2017 | Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement | 原採認標準 |
| 454 | In Vitro Diagnostics 體外診斷醫 | TFDA-01902 | CLSI | VET01 | 2018 | Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 455 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01996 | CLSI | EP07 | 2018 | Interference Testing in Clinical Chemistry | 原採認標準 |
| 456 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01997 | CLSI | M23 | 2018 | Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters | 原採認標準 |
| 457 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01998 | CLSI | M02 | 2018 | Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard -Twelfth Edition | 原採認標準 |
| 458 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-01999 | CLSI | M07 | 2018 | Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard -Tenth Edition | 原採認標準 |
| 459 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02000 | CLSI | M11 | 2018 | Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard | 原採認標準 |
| 460 | In Vitro Diagnostics 體外診斷醫 | TFDA-02001 | CLSI | M24 | 2018 | Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 461 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02002 | ISO | ISO 6710:2017 | 2017 | Single-use containers for human venous blood specimen collection | 原採認標準 |
| 462 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02003 | CLSI | M45 | 2016 | Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline | 原採認標準 |
| 463 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02004 | IEC | IEC 61010-2-101:201 8 | 2018 | Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-101: Particular Requirements for in Vitro Diagnostic (IVD) Medical Equipment | 原採認標準 |
| 464 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02005 | CLSI | QMS24 | 2016 | Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality | 原採認標準 |
| 465 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02006 | CLSI | MM17 | 2018 | Validation and Verification of Multiplex Nucleic Acid Assays | 原採認標準 |
| 466 | In Vitro Diagnostics 體外診斷醫 | TFDA-02007 | CLSI | MM23 | 2015 | Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 療器材 | | | | | | |
| 467 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02008 | ISO | ISO 17511:2020 | 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 |
| 468 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02009 | ISO | ISO 20776-1:2019 | 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 |
| 469 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02010 | IEC | IEC 61010-1:2010/A MD1:2016/COR1 :2019 | 2019 | Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements | 原採認標準 |
| 470 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02127 | ISO | ISO/TS 20914 First edition 2019-07 | 2019 | Medical laboratories - Practical guidance for the estimation of measurement uncertainty | 110 年度新增 採認標準 |
| 471 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02128 | CLSI | EP35 | 2019 | Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures-1st Edition | 110 年度新增 採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

| | | | | | | | |
|-----|-----------------------------------------|------------|------------|----------------------------|------|----------------------------------------------------------------------------------------------------------------------------------------|------------------|
| 472 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02129 | CEN ISO | EN ISO 23640:2015 | 2011 | In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents | 110 年度新增 採認標準 |
| 473 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02130 | CLSI | CLSI M36-A | 2004 | Clinical Use and Interpretation of Serologic Tests for Toxoplasma gondii, 1st Edition | 110 年度新增 採認標準 |
| 474 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02131 | CLSI | CLSI M62 1st Edition | 2020 | Performance Standards for Susceptibility Testing of Mycobacteria Nocardia spp. and other Aerobic Actinomycetes | 110 年度新增 採認標準 |
| 475 | In Vitro Diagnostics 體外診斷醫 療器材 | TFDA-02132 | CLSI | CLSI POCT05 2nd Edition | 2020 | Performance Metrics for Continuous Interstitial Glucose Monitoring | 110 年度新增 採認標準 |
| 476 | Materials 材 料 | TFDA-00071 | ISO | ISO 5832-6:1997 | 1997 | Implants for surgery -- Metallic materials -- Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy | 原採認標準 |
| 477 | Materials 材 料 | TFDA-00394 | ISO | ISO 5832-5:2005 | 2005 | Implants for surgery -- Metallic materials -- Part 5: Wrought cobalt-chromium-tungsten-nickel alloy | 原採認標準 |
| 478 | Materials 材 料 | TFDA-00399 | ISO | ISO 16428:2005 | 2005 | Implants for surgery – Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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|-----|--------------|------------|------|-----------------------|------|------------------------------------------------------------------------------------------------------------------------|-------|
| | | | | | | medical devices | |
| 479 | Materials 材料 | TFDA-00539 | CNS | CNS 13382-1 | 2004 | 外科體內植入物－金屬材料－鍛造不鏽鋼 | 原採認標準 |
| 480 | Materials 材料 | TFDA-00540 | CNS | CNS 13382-2 | 2004 | 外科體內植入物－金屬材料－鍛造鈷－鉻－鎢－鎳合金 | 原採認標準 |
| 481 | Materials 材料 | TFDA-00541 | CNS | CNS 13382-3 | 2004 | 外科體內植入物－金屬材料－鍛造鈷－鎳－鉻－鈾－鎢－鐵合金 | 原採認標準 |
| 482 | Materials 材料 | TFDA-00542 | CNS | CNS 13382-4 | 2004 | 外科體內植入物－金屬材料－鍛造鈷－鎳－鉻－鈾合金 | 原採認標準 |
| 483 | Materials 材料 | TFDA-00543 | CNS | CNS 13382-5 | 2004 | 外科體內植入物－金屬材料－鈦金屬 | 原採認標準 |
| 484 | Materials 材料 | TFDA-00544 | CNS | CNS 13382-6 | 2004 | 外科體內植入物－金屬材料－鑄造鈷-鉻-鈾合金 | 原採認標準 |
| 485 | Materials 材料 | TFDA-00545 | CNS | CNS 13382-7 | 2004 | 外科體內植入物－金屬材料－鍛造鈦－6 鋁－4 鈮合金 | 原採認標準 |
| 486 | Materials 材料 | TFDA-00546 | CNS | CNS 13382-8 | 2004 | 外科體內植入物－金屬材料－可鍛及冷作加工鈷－鉻－鎳－鈾－鐵合金 | 原採認標準 |
| 487 | Materials 材料 | TFDA-00955 | CEN | EN 29073-3:1992 | 1992 | Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation | 原採認標準 |
| 488 | Materials 材料 | TFDA-00957 | ISO | ISO 9073-10:2003 | 2003 | Textiles -- Test methods for nonwovens -- Part 10: Lint and other particles generation in the dry state | 原採認標準 |
| 489 | Materials 材料 | TFDA-01091 | ASTM | ASTM F1713-08/(R)2013 | 2013 | Standard Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

| | | | | | | | |
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| 490 | Materials 材料 | TFDA-01096 | ASTM | ASTM F562-13 | 2013 | Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035) | 原採認標準 |
| 491 | Materials 材料 | TFDA-01099 | ISO | ISO 139:2005/Amd 1:2011 | 2011 | Textiles -- Standard atmospheres for conditioning and testing | 原採認標準 |
| 492 | Materials 材料 | TFDA-01581 | ASTM | ASTM D3772 - 15(2021) | 2021 | Standard Specification for Industrial Rubber Finger Cots | 原採認標準 |
| 493 | Materials 材料 | TFDA-01583 | ASTM | ASTM F1185-03/(R)2014 | 2014 | Standard Specification for Composition of Hydroxylapatite for Surgical Implants | 原採認標準 |
| 494 | Materials 材料 | TFDA-01584 | ASTM | ASTM F136 - 13(2021)e1 | 2021 | Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) | 原採認標準 |
| 495 | Materials 材料 | TFDA-01588 | ASTM | ASTM F2224 - 09(2020) | 2020 | Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants | 原採認標準 |
| 496 | Materials 材料 | TFDA-01590 | ASTM | ASTM F2347-15 | 2015 | Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications | 原採認標準 |
| 497 | Materials 材料 | TFDA-01591 | ASTM | ASTM F2565 - | 2021 | Standard Guide for Extensively | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 料 | | | 21 | | Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications | |
| 498 | Materials 材 料 | TFDA-01592 | ASTM | ASTM F2695 - 12(2020) | 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 |
| 499 | Materials 材 料 | TFDA-01593 | ASTM | ASTM F2820 - 12(2021)e1 | 2021 | Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications | 原採認標準 |
| 500 | Materials 材 料 | TFDA-01594 | ASTM | ASTM F2971 - 13(2021) | 2021 | Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing | 原採認標準 |
| 501 | Materials 材 料 | TFDA-01595 | ASTM | ASTM F3087-15 | 2015 | Standard Specification for Acrylic Molding Resins for Medical Implant Applications | 原採認標準 |
| 502 | Materials 材 料 | TFDA-01596 | ISO | ISO 13356:2015 | 2015 | Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP). | 原採認標準 |
| 503 | Materials 材 料 | TFDA-01597 | ISO | ISO 14708-1:2014 | 2014 | Implants for surgery — Active implantable medical devices —Part 1: General requirements for safety, marking and for information to be provided by the manufacturer | 原採認標準 |
| 504 | Materials 材 料 | TFDA-01598 | ISO | ISO 5832-1:2016 | 2016 | Implants for surgery - Metallic materials - Part 1: Wrought stainless steel | 原採認標準 |
| 505 | Materials 材 料 | TFDA-01599 | ISO | ISO 5832-11:2014 | 2014 | Implants for surgery -- Metallic materials -- Part 11: Wrought titanium 6-aluminium 7-niobium alloy | 原採認標準 |
| 506 | Materials 材 | TFDA-01600 | ISO | ISO 5832-3:2016 | 2016 | Implants for surgery - Metallic materials - Part 3: | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 料 | | | | | Wrought titanium 6-aluminium 4-vanadium alloy | |
| 507 | Materials 材 料 | TFDA-01601 | ISO | ISO 5832-4:2014 | 2014 | Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy - Third Edition | 原採認標準 |
| 508 | Materials 材 料 | TFDA-01602 | ISO | ISO 5832-7:2016 | 2016 | Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobaltchromium- nickel-molybdenum-iron alloy | 原採認標準 |
| 509 | Materials 材 料 | TFDA-01603 | ISO | ISO/ASTM 52900:2015 | 2015 | Standard Terminology for Additive Manufacturing – General Principles – Terminology | 原採認標準 |
| 510 | Materials 材 料 | TFDA-01604 | ISO | ISO/ASTM 52921:2013 | 2013 | Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies | 原採認標準 |
| 511 | Materials 材 料 | TFDA-01805 | ASTM | ASTM D412 - 16(2021) | 2021 | Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension | 原採認標準 |
| 512 | Materials 材 料 | TFDA-01806 | ASTM | ASTM F1925-17 | 2017 | Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants | 原採認標準 |
| 513 | Materials 材 料 | TFDA-01807 | ASTM | ASTM F2026-17 | 2017 | Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications | 原採認標準 |
| 514 | Materials 材 料 | TFDA-01808 | ASTM | ASTM F2052-15 | 2015 | Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment | 原採認標準 |
| 515 | Materials 材 | TFDA-01810 | ASTM | ASTM F2459-18 | 2018 | Standard Test Method for Extracting Residue from | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 料 | | | | | Metallic Medical Components and Quantifying via Gravimetric Analysis | |
| 516 | Materials 材 料 | TFDA-01813 | ISO | ISO 10974:2018 | 2018 | Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device | 原採認標準 |
| 517 | Materials 材 料 | TFDA-01814 | ISO | ISO 5832-2:2018 | 2018 | Implants for Surgery - Metallic Materials - Part 2: Unalloyed Titanium | 原採認標準 |
| 518 | Materials 材 料 | TFDA-01815 | ISO | ISO/ASTM 52901:2017 | 2017 | Standard Guide for Additive Manufacturing—General Principles—Requirements for Purchased AM Parts | 原採認標準 |
| 519 | Materials 材 料 | TFDA-01903 | AAMI | AAMI ST65:2008 (R2018) | 2018 | Processing of reusable surgical textiles for use in health care facilities | 原採認標準 |
| 520 | Materials 材 料 | TFDA-01904 | ASTM | ASTM F2393 - 12(2020) | 2020 | Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications | 原採認標準 |
| 521 | Materials 材 料 | TFDA-01905 | ASTM | ASTM F621 - 12(2021)e1 | 2021 | Standard Specification for Stainless Steel Forgings for Surgical Implants | 原採認標準 |
| 522 | Materials 材 料 | TFDA-01906 | ASTM | ASTM F1581 - 08(2020) | 2020 | Standard Specification for Composition of Anorganic Bone for Surgical Implants | 原採認標準 |
| 523 | Materials 材 料 | TFDA-01907 | ASTM | ASTM F3260 - 18 | 2018 | Standard Test Method for Determining the Flexural Stiffness of Medical Textiles | 原採認標準 |
| 524 | Materials 材 料 | TFDA-02011 | ISO | ISO 5834-3:2019 | 2019 | Implants for surgery – Ultra-high molecular-weight polyethylene – Part 3:Accelerated ageing methods | 原採認標準 |
| 525 | Materials 材 | TFDA-02012 | ISO | ISO 5834-4:2019 | 2019 | Implants for surgery – Ultra-high molecular-weight | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 料 | | | | | polyethylene – Part 4:Oxidation index measurement method | |
| 526 | Materials 材 料 | TFDA-02013 | ISO | ISO 5834-5:2019 | 2019 | Implants for surgery – Ultra-high molecular-weight polyethylene – Part 5:Morphology assessment method | 原採認標準 |
| 527 | Materials 材 料 | TFDA-02014 | ISO | ISO 5832-9:2019 | 2019 | Implants for surgery -- Metallic materials -- Part 9:Wrought high nitrogen stainless steel | 原採認標準 |
| 528 | Materials 材 料 | TFDA-02015 | ISO | ISO 5832-12:2019 | 2019 | Implants for surgery -- Metallic materials -- Part 12:Wrought cobalt-chromium-molybdenum alloy | 原採認標準 |
| 529 | Materials 材 料 | TFDA-02016 | ISO | ISO 5834-1:2019 | 2019 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 1:Powder form | 原採認標準 |
| 530 | Materials 材 料 | TFDA-02017 | ISO | ISO 6474-1:2019 | 2019 | Implants for surgery -- Ceramic materials -- Part 1:Ceramic materials based on high purity alumina | 原採認標準 |
| 531 | Materials 材 料 | TFDA-02018 | ISO | ISO 811:2018 | 2018 | Textiles - Determination of resistance to water penetration - Hydrostatic pressure test | 原採認標準 |
| 532 | Materials 材 料 | TFDA-02019 | ASTM | ASTM F2063-18 | 2018 | Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants | 原採認標準 |
| 533 | Materials 材 料 | TFDA-02020 | ISO | ISO 5834-2:2019 | 2019 | Implants for surgery -- Ultra-high-molecular-weight polyethylene -- Part 2: Moulded forms | 原採認標準 |
| 534 | Materials 材 料 | TFDA-02021 | ASTM | ASTM F2313-18 | 2018 | Standard Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 535 | Materials 材料 | TFDA-02022 | ASTM | ASTM F3268-18a | 2018 | Standard Guide for in vitro Degradation Testing of Absorbable Metals | 原採認標準 |
| 536 | Materials 材料 | TFDA-02023 | ISO | ISO/ASTM 52910-18 | 2018 | Additive manufacturing - Design - Requirements, guidelines and recommendations | 原採認標準 |
| 537 | Materials 材料 | TFDA-02024 | ASTM | ASTM F3301-18a | 2018 | Standard for Additive Manufacturing—Post Processing Methods—Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion. | 原採認標準 |
| 538 | Materials 材料 | TFDA-02025 | ASTM | ASTM F3302-18 | 2018 | Standard for Additive Manufacturing—Finished Part Properties—Standard Specification for Titanium Alloys via Powder Bed Fusion | 原採認標準 |
| 539 | Materials 材料 | TFDA-02026 | ISO/ASTM | ISO/ASTM 52904:2019 | 2019 | Standard for Additive Manufacturing—Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications. | 原採認標準 |
| 540 | Materials 材料 | TFDA-02027 | ISO | ISO 13782:2019 | 2019 | Implants for surgery -- Metallic materials -- Unalloyed tantalum for surgical implant applications | 原採認標準 |
| 541 | Materials 材料 | TFDA-02028 | ISO | ISO 13938-1:2019 | 2019 | Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension | 原採認標準 |
| 542 | Materials 材料 | TFDA-02029 | ASTM | ASTM F1091 - 20 | 2020 | Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 543 | Materials 材料 | TFDA-02030 | ASTM | ASTM F139 - 19 | 2019 | Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673) | 原採認標準 |
| 544 | Materials 材料 | TFDA-02031 | ASTM | ASTM F1537 - 20 | 2020 | Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) | 原採認標準 |
| 545 | Materials 材料 | TFDA-02032 | ASTM | ASTM F2129 - 19a | 2019 | Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices | 原採認標準 |
| 546 | Materials 材料 | TFDA-02033 | ASTM | ASTM F3208 - 20 | 2020 | Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices | 原採認標準 |
| 547 | Materials 材料 | TFDA-02133 | ASTM | D638 - 14 | 2014 | Standard Test Method for Tensile Properties of Plastics | 110 年度新增採認標準 |
| 548 | Materials 材料 | TFDA-02134 | ASTM | E647 - 15e1 | 2015 | Standard Test Method for Measurement of Fatigue Crack Growth Rates | 110 年度新增採認標準 |
| 549 | Materials 材料 | TFDA-02135 | ASTM | F2633-19 | 2019 | Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants | 110 年度新增採認標準 |
| 550 | Materials 材料 | TFDA-02136 | ASTM | F3321-19 | 2019 | Standard Guide for Methods of Extraction of Test Soils for the Validation of Cleaning Methods for | 110 年度新增採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 551 | Materials 材 料 | TFDA-02137 | ASTM ISO | ISO/ASTM 52907:2019 | 2019 | Additive Manufacturing - Feedstock materials - Methods to characterize metal powders | 110 年度新增 採認標準 |
| 552 | Materials 材 料 | TFDA-02138 | ASTM ISO | ISO/ASTM 52911-1:2019 | 2019 | Additive Manufacturing - Design - Part 1: Laser-based powder bed fusion of metals | 110 年度新增 採認標準 |
| 553 | Materials 材 料 | TFDA-02139 | ASTM ISO | ISO/ASTM 52911-2:2019 | 2019 | Additive Manufacturing - Design - Part 2: Laser-based powder bed fusion of polymers | 110 年度新增 採認標準 |
| 554 | Materials 材 料 | TFDA-02140 | ASTM ISO | ISO/ASTM 52902:2019 | 2019 | Additive Manufacturing - Test Artifacts - Geometric capability assessment of additive manufacturing systems | 110 年度新增 採認標準 |
| 555 | Materials 材 料 | TFDA-02141 | ASTM | F3335-20 | 2020 | Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion | 110 年度新增 採認標準 |
| 556 | Materials 材 料 | TFDA-02142 | ASTM ISO | ASTM ISO 52915 Third edition 2020-03 | 2020 | Specification for additive manufacturing file format (AMF) Version 1.2 | 110 年度新增 採認標準 |
| 557 | Materials 材 料 | TFDA-02143 | ASTM | ASTM F2181-20 | 2020 | Standard Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants | 110 年度新增 採認標準 |
| 558 | Materials 材 料 | TFDA-02144 | ASTM ISO | ASTM ISO TR 52912 First edition 2020-09 | 2020 | Additive manufacturing - Design - Functionally graded additive manufacturing | 110 年度新增 採認標準 |
| 559 | Materials 材 料 | TFDA-02145 | ASTM | ASTM F620-20 | 2020 | Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition | 110 年度新增 採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 560 | Materials 材料 | TFDA-02146 | ASTM | ASTM F2977-20 | 2020 | Standard Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants | 110 年度新增採認標準 |
| 561 | Materials 材料 | TFDA-02147 | ASTM | ASTM F3044-20 | 2020 | Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants | 110 年度新增採認標準 |
| 562 | Materials 材料 | TFDA-02148 | ASTM | ASTM F629-20 | 2020 | Standard Practice for Radiography of Cast Metallic Surgical Implants | 110 年度新增採認標準 |
| 563 | Materials 材料 | TFDA-02149 | ASTM | ASTM F961-20 | 2020 | Standard Specification for 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035) | 110 年度新增採認標準 |
| 564 | Materials 材料 | TFDA-02150 | ASTM | ASTM F3434-20 | 2020 | Guide for Additive manufacturing - Installation/Operation and Performance Qualification (IQ/OQ/PQ) of Laser-Beam Powder Bed Fusion Equipment for Production Manufacturing | 110 年度新增採認標準 |
| 565 | Materials 材料 | TFDA-02151 | ASTM | ASTM F2895-20 | 2020 | Standard Practice for Digital Radiography of Cast Metallic Implants | 110 年度新增採認標準 |
| 566 | Materials 材料 | TFDA-02152 | ASTM ISO | ASTM ISO 52903-1 First edition 2020-04 | 2020 | Additive manufacturing - Material extrusion-based additive manufacturing of plastic materials - Part 1: Feedstock materials | 110 年度新增採認標準 |
| 567 | Materials 材料 | TFDA-02153 | ASTM | ASTM F1472-20a | 2020 | Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400) | 110 年度新增採認標準 |
| 568 | Materials 材料 | TFDA-02154 | ASTM | ASTM F3333-20 | 2020 | Standard Specification for Chopped Carbon Fiber | 110 年度新增 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 料 | | | | | Reinforced (CFR) Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications | 採認標準 |
| 569 | Materials 材 料 | TFDA-02155 | ASTM | ASTM F640-20 | 2020 | Standard Test Methods for Determining Radiopacity for Medical Use | 110 年度新增 採認標準 |
| 570 | Materials 材 料 | TFDA-02156 | ASTM | ASTM F67-13(2017) | 2017 | Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700) | 110 年度新增 採認標準 |
| 571 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-00878 | IEC | IEC 60601-2-18 ed3.0 : 2009 | 2009 | Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment | 原採認標準 |
| 572 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01252 | CNS | CNS 14194 | 1998 | 血液透析器、血液過濾器、血液濃縮器之體外迴 路管 (Extracorporeal blood circuit for haemodialysers hasmofilters and haemoconcentrators) | 原採認標準 |
| 573 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01325 | CNS | CNS 6629 | 2007 | 天然乳膠衛生套 (Natural latex rubber condoms - Requirements and test methods)(IDT: ISO 4074:2015) | 原採認標準 |
| 574 | ObGyn/Gastr oenterology | TFDA-01605 | ASTM | ASTM D1894-14 | 2014 | Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheetting | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 胃腸病科學 及泌尿科學/ 婦產科學 | | | | | | |
| 575 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01607 | ISO | ISO 4074:2015 | 2015 | Natural latex rubber condoms - Requirements and test methods | 原採認標準 |
| 576 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01608 | ISO | ISO 7439:2015 | 2015 | Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2015) | 原採認標準 |
| 577 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01609 | ISO | ISO 8009:2014 | 2014 | Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests | 原採認標準 |
| 578 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01610 | ISO | ISO 8637-1:2017 | 2017 | Extracorporeal systems for blood purification -- Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators | 原採認標準 |
| 579 | ObGyn/Gastr | TFDA-01763 | ASTM | ASTM F1828-17 | 2017 | Standard Specification for Ureteral Stents | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | | | | | | |
| 580 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01816 | IEC | IEC 60601-2-16:2018 | 2018 | Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment. | 原採認標準 |
| 581 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01817 | ISO | ISO 29943-1:2017 | 2017 | Condoms—Guidance on clinical studies—Part 1: Male condoms, clinical function studies based on self-reports | 原採認標準 |
| 582 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-01818 | ISO | ISO 29943-2:2017 | 2017 | Condoms—Guidance on clinical studies—Part 2: Female condoms, clinical function studies | 原採認標準 |
| 583 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02034 | ISO | ISO 8637-2:2018 | 2018 | Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 584 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02035 | ISO | ISO 23500-3:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies | 原採認標準 |
| 585 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02036 | ISO | ISO 23500-2:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies | 原採認標準 |
| 586 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02037 | AAMI | AAMI/ISO 23500-1:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements | 原採認標準 |
| 587 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02038 | EN | ISO 20695:2020 | 2020 | Enteral feeding systems — Design and testing | 原採認標準 |
| 588 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ | TFDA-02039 | ISO | ISO 23500-5:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 婦產科學 | | | | | | |
| 589 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02040 | ISO | ISO 23500-4:2019 | 2019 | Preparation and quality management of fluids for haemodialysis and related therapies - Part 4: Concentrates for haemodialysis and related therapies | 原採認標準 |
| 590 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02041 | ISO | ISO 8600-3:2019 | 2019 | Endoscopes — Medical endoscopes and endotherapy devices —Part 3: Determination of field of view and direction of view of endoscopes with optics | 原採認標準 |
| 591 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02042 | AAMI | AAMI RD47-2020 | 2020 | Reprocessing of hemodialyzers | 原採認標準 |
| 592 | ObGyn/Gastroenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02157 | CIE ISO | ISO/CIE 11664-1:2019 | 2019 | Colorimetry - Part 1: CIE standard colorimetric observers | 110 年度新增 採認標準 |
| 593 | ObGyn/Gastroenterology 胃腸病科學 | TFDA-02158 | CIE ISO | ISO/CIE 11664-3:2019 | 2019 | Colorimetry - Part 3: CIE tristimulus values | 110 年度新增 採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 及泌尿科學/ 婦產科學 | | | | | | |
| 594 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02159 | CIE ISO | ISO/CIE 11664-4:2019 | 2019 | Colorimetry - Part 4: CIE 1976 L*a*b* colour space | 110 年度新增 採認標準 |
| 595 | ObGyn/Gastr oenterology 胃腸病科學 及泌尿科學/ 婦產科學 | TFDA-02160 | ISO | ISO 8600-5 Second Edition 2020-10 | 2020 | Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics | 110 年度新增 採認標準 |
| 596 | Ophthalmic 眼科學 | TFDA-00990 | CNS | CNS 12446 | 1988 | 軟性隱形眼鏡片 | 原採認標準 |
| 597 | Ophthalmic 眼科學 | TFDA-00995 | ISO | ISO 8980-4:2006 | 2006 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 4: Specifications and test methods for anti-reflective coatings | 原採認標準 |
| 598 | Ophthalmic 眼科學 | TFDA-00996 | ISO | ISO 8980-5:2005 | 2005 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant | 原採認標準 |
| 599 | Ophthalmic 眼科學 | TFDA-01327 | CNS | CNS 15448-1 | 2011 | 眼科光學－未切邊之眼鏡鏡片成品－第 1 部：單光與多焦點眼鏡鏡片規格 (Ophthalmic optics - Uncut finished spectacle lenses - Part 1: | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | Specifications for single-vision and multifocal lenses)(IDT: ISO 8980-1:2004) | |
| 600 | Ophthalmic 眼科學 | TFDA-01328 | CNS | CNS 15448-2 | 2011 | 眼科光學－未切邊之眼鏡鏡片成品－第 2 部：漸進多焦點眼鏡鏡片規格 (Ophthalmic optics - Uncut finished spectacle lenses - Part 2: Specifications for progressive lenses) (IDT: ISO 8980-2:2004) | 原採認標準 |
| 601 | Ophthalmic 眼科學 | TFDA-01331 | ISO | ISO 10936-2:2010 | 2010 | Optics and photonics -- Operation microscopes -- Part 2: Light hazard from operation microscopes used in ocular surgery | 原採認標準 |
| 602 | Ophthalmic 眼科學 | TFDA-01335 | ISO | ISO 11979-3:2012 | 2012 | Ophthalmic Implants - Intraocular Lenses - Part 3: Mechanical Properties and Test Methods - Third Edition | 原採認標準 |
| 603 | Ophthalmic 眼科學 | TFDA-01336 | ISO | ISO 11979-5:2020 | 2020 | Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility | 原採認標準 |
| 604 | Ophthalmic 眼科學 | TFDA-01341 | ISO | ISO 11987:2012 | 2012 | Ophthalmic optics -- Contact lenses -- Determination of shelf-life | 原採認標準 |
| 605 | Ophthalmic 眼科學 | TFDA-01342 | ISO | ISO 14534:2011 | 2011 | Ophthalmic optics -- Contact lenses and contact lens care products -- Fundamental requirements | 原採認標準 |
| 606 | Ophthalmic 眼科學 | TFDA-01344 | ISO | ISO 8980-3:2013 | 2013 | Ophthalmic optics -- Uncut finished spectacle lenses -- Part 3: Transmittance specifications and test methods | 原採認標準 |
| 607 | Ophthalmic 眼科學 | TFDA-01345 | ISO | ISO 9394:2012 | 2012 | Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | biocompatibility by ocular study with rabbit eyes | |
| 608 | Ophthalmic 眼科學 | TFDA-01346 | ANSI | ANSI Z80.7-2013 (R2018) | 2018 | Ophthalmic Optics – Intraocular Lenses | 原採認標準 |
| 609 | Ophthalmic 眼科學 | TFDA-01611 | ISO | ISO 18189:2016 | 2016 | Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/ solution interactions | 原採認標準 |
| 610 | Ophthalmic 眼科學 | TFDA-01612 | ANSI | ANSI Z80.36-2021 | 2021 | Ophthalmic – Light Hazard Protection for Ophthalmic Instruments | 原採認標準 |
| 611 | Ophthalmic 眼科學 | TFDA-01615 | ISO | ISO 11979-2:2014 | 2014 | Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods - Second Edition | 原採認標準 |
| 612 | Ophthalmic 眼科學 | TFDA-01616 | ISO | ISO 14730:2014 | 2014 | Ophthalmic optics -- Contact lens care products -- Antimicrobial preservative efficacy testing and guidance on determining discard date | 原採認標準 |
| 613 | Ophthalmic 眼科學 | TFDA-01819 | IEC | IEC 80601-2-58:2014 +AMD1:2016 CSV | 2016 | 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 |
| 614 | Ophthalmic 眼科學 | TFDA-01820 | ISO | ISO 10936-1:2017 | 2017 | Optics and photonics - Operation microscopes - Part 1: Requirements and test methods | 原採認標準 |
| 615 | Ophthalmic 眼科學 | TFDA-01821 | ISO | ISO 11979-10:2018 | 2018 | Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 616 | Ophthalmic 眼科學 | TFDA-01823 | ISO | ISO 11979-8:2017 | 2017 | Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements | 原採認標準 |
| 617 | Ophthalmic 眼科學 | TFDA-01824 | ISO | ISO 11981:2017 | 2017 | Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses | 原採認標準 |
| 618 | Ophthalmic 眼科學 | TFDA-01825 | ISO | ISO 11986:2017 | 2017 | Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release | 原採認標準 |
| 619 | Ophthalmic 眼科學 | TFDA-01826 | ISO | ISO 15798:2013+A1:2 017 | 2017 | Ophthalmic implants—Ophthalmic viscosurgical devices— Amendment 1 | 原採認標準 |
| 620 | Ophthalmic 眼科學 | TFDA-01827 | ISO | ISO 18369-1:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications | 原採認標準 |
| 621 | Ophthalmic 眼科學 | TFDA-01828 | ISO | ISO 18369-2:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 2: Tolerances | 原採認標準 |
| 622 | Ophthalmic 眼科學 | TFDA-01829 | ISO | ISO 18369-3:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 3: Measurement methods | 原採認標準 |
| 623 | Ophthalmic 眼科學 | TFDA-01830 | ISO | ISO 18369-4:2017 | 2017 | Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials | 原採認標準 |
| 624 | Ophthalmic 眼科學 | TFDA-01831 | ISO | ISO 8980-1:2017 | 2017 | Ophthalmic optics - Uncut finished spectacle lenses - Part 1: Specifications for single-vision and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | multifocal lenses | |
| 625 | Ophthalmic 眼科學 | TFDA-01832 | ISO | ISO 8980-2:2017 | 2017 | Ophthalmic optics - Uncut finished spectacle lenses - Part 2: Specifications for power-variation lenses | 原採認標準 |
| 626 | Ophthalmic 眼科學 | TFDA-02043 | ISO | ISO 11979-7:2018 | 2018 | Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia | 原採認標準 |
| 627 | Ophthalmic 眼科學 | TFDA-02044 | ISO | ISO 11979-1:2018 | 2018 | Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary - Third Edition | 原採認標準 |
| 628 | Ophthalmic 眼科學 | TFDA-02045 | ASTM | ASTM D882-18 | 2018 | Standard Test Method for Tensile Properties of Thin Plastic Sheeting | 原採認標準 |
| 629 | Ophthalmic 眼科學 | TFDA-02161 | ISO | ISO 15004-2:2007 | 2007 | Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection | 110 年度新增採認標準 |
| 630 | Ophthalmic 眼科學 | TFDA-02162 | ISO | ISO 16971:2015 | 2015 | Ophthalmic instruments — Optical coherence tomograph for the posterior segment of the human eye | 110 年度新增採認標準 |
| 631 | Ophthalmic 眼科學 | TFDA-02163 | ISO | ISO 15004-1:2020 | 2020 | Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments | 110 年度新增採認標準 |
| 632 | Ophthalmic 眼科學 | TFDA-02164 | ANSI | ANSI Z80.20-2016 | 2016 | Contact Lenses - Standard Terminology, Tolerances Measurements and Physiochemical Properties | 110 年度新增採認標準 |
| 633 | Ophthalmic 眼科學 | TFDA-02165 | ISO | ISO 16672 Third edition 2020-06 | 2020 | Ophthalmic implants - Ocular endotamponades | 110 年度新增採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 634 | Ophthalmic 眼科學 | TFDA-02166 | ISO | ISO TR 22979 Second Edition 2017-05 | 2017 | Ophthalmic implants - Intraocular Lenses - Guidance on assessment of the need for clinical investigation of intraocular lens design modifications | 110 年度新增 採認標準 |
| 635 | Orthopaedics 骨科學 | TFDA-00082 | ISO | ISO 5838-2:199 1 | 1991 | Implants for surgery -- Skeletal pins and wires -- Part 2: Steinmann skeletal pins -- Dimensions | 原採認標準 |
| 636 | Orthopaedics 骨科學 | TFDA-00083 | ISO | ISO 5838-3:199 3 | 1993 | Implants for surgery -- Skeletal pins and wires -- Part 3: Kirschner skeletal wires | 原採認標準 |
| 637 | Orthopaedics 骨科學 | TFDA-00884 | ISO | ISO 7207-1:2007 | 2007 | Implants for surgery -- Components for partial and total knee joint prostheses -- Part 1: Classification, definitions and designation of dimensions | 原採認標準 |
| 638 | Orthopaedics 骨科學 | TFDA-00885 | ISO | ISO 14243-1:2009/A MD 1:2020 | 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 |
| 639 | Orthopaedics 骨科學 | TFDA-00887 | ISO | ISO 14602:2010 | 2010 | Non-active surgical implants -- Implants for osteosynthesis -- Particular requirements | 原採認標準 |
| 640 | Orthopaedics 骨科學 | TFDA-01363 | ISO | ISO 14630:2012 | 2012 | Non-active surgical implants -- General requirements | 原採認標準 |
| 641 | Orthopaedics 骨科學 | TFDA-01364 | ISO | ISO 5833:2002 | 2002 | Implants for Surgery - Acrylic Resin Cements - Second Edition | 原採認標準 |
| 642 | Orthopaedics 骨科學 | TFDA-01365 | ISO | ISO 5838-1:2013 | 2013 | Implants for surgery -- Metallic skeletal pins and wires -- Part 1: General requirements | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 643 | Orthopaedics 骨科學 | TFDA-01369 | ASTM | ASTM F1820-13 | 2013 | Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices | 原採認標準 |
| 644 | Orthopaedics 骨科學 | TFDA-01380 | ASTM | ASTM F2665 - 21 | 2021 | Standard Specification for Total Ankle Replacement Prosthesis | 原採認標準 |
| 645 | Orthopaedics 骨科學 | TFDA-01382 | ASTM | ASTM F2996 - 20 | 2020 | Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems | 原採認標準 |
| 646 | Orthopaedics 骨科學 | TFDA-01617 | ASTM | ASTM D2990-17 | 2017 | Standard Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics | 原採認標準 |
| 647 | Orthopaedics 骨科學 | TFDA-01618 | ASTM | ASTM D790-17 | 2017 | Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials | 原採認標準 |
| 648 | Orthopaedics 骨科學 | TFDA-01619 | ASTM | ASTM F116 - 12(2021) | 2021 | Standard Specification for Medical Screwdriver Bits | 原採認標準 |
| 649 | Orthopaedics 骨科學 | TFDA-01625 | ASTM | ASTM F2091-15 | 2015 | Standard Specification for Acetabular Prostheses | 原採認標準 |
| 650 | Orthopaedics 骨科學 | TFDA-01626 | ASTM | ASTM F2180-17 | 2017 | Standard Specification for Metallic Implantable Strands and Cables | 原採認標準 |
| 651 | Orthopaedics 骨科學 | TFDA-01630 | ASTM | ASTM F2582 - 20 | 2020 | Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components | 原採認標準 |
| 652 | Orthopaedics 骨科學 | TFDA-01631 | ASTM | ASTM F2887-17 | 2017 | Standard Specification for Total Elbow Prostheses | 原採認標準 |
| 653 | Orthopaedics 骨科學 | TFDA-01632 | ASTM | ASTM F2979 - 20 | 2020 | Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | Metal-on-Metal and other Hard-on-Hard Hip Prostheses | |
| 654 | Orthopaedics 骨科學 | TFDA-01633 | ASTM | ASTM F3161-16 | 2016 | Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions | 原採認標準 |
| 655 | Orthopaedics 骨科學 | TFDA-01634 | ASTM | ASTM F451 - 21 | 2021 | Standard Specification for Acrylic Bone Cement | 原採認標準 |
| 656 | Orthopaedics 骨科學 | TFDA-01636 | ISO | ISO 14242-2:2016 | 2016 | Implants for surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement | 原採認標準 |
| 657 | Orthopaedics 骨科學 | TFDA-01637 | ISO | ISO 14243-2:2016 | 2016 | Implants for surgery - Wear of total knee-joint prostheses - Part 2: Methods of measurement | 原採認標準 |
| 658 | Orthopaedics 骨科學 | TFDA-01639 | ISO | ISO 21535:2009/Amd 1:2016 | 2016 | Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants | 原採認標準 |
| 659 | Orthopaedics 骨科學 | TFDA-01640 | ISO | ISO 21536:2007/Amd 1:2014 | 2014 | Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants - Amendment 1 | 原採認標準 |
| 660 | Orthopaedics 骨科學 | TFDA-01641 | ISO | ISO 7207-2:2011/AM D 1:2016 | 2016 | Implants for surgery - Components for partial and total knee joint prostheses - Part 2: Articulating surfaces made of metal, ceramic and plastics materials | 原採認標準 |
| 661 | Orthopaedics 骨科學 | TFDA-01833 | ASTM | ASTM D732-17 | 2017 | Standard Test Method for Shear Strength of Plastics by Punch Tool | 原採認標準 |
| 662 | Orthopaedics | TFDA-01836 | ASTM | ASTM F1541 - | 2017 | Standard Specification and Test Methods for | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 骨科學 | | | 17 | | External Skeletal Fixation Devices | |
| 663 | Orthopaedics 骨科學 | TFDA-01838 | ASTM | ASTM F1829-17 | 2017 | Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear | 原採認標準 |
| 664 | Orthopaedics 骨科學 | TFDA-01839 | ASTM | ASTM F1978 - 18 | 2018 | Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser | 原採認標準 |
| 665 | Orthopaedics 骨科學 | TFDA-01840 | ASTM | ASTM F2028-17 | 2017 | Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation | 原採認標準 |
| 666 | Orthopaedics 骨科學 | TFDA-01842 | ASTM | ASTM F2502 - 17 | 2017 | Test Methods For Intervertebral Body Fusion Devices | 原採認標準 |
| 667 | Orthopaedics 骨科學 | TFDA-01843 | ISO | ISO 13175-3:2012 | 2012 | Implants for surgery - Calcium phosphates - Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes | 原採認標準 |
| 668 | Orthopaedics 骨科學 | TFDA-01908 | ASTM | ASTM F2267 - 04(2018) | 2018 | Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression | 原採認標準 |
| 669 | Orthopaedics 骨科學 | TFDA-01909 | ASTM | ASTM F1714 - 96(2018) | 2018 | Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices. | 原採認標準 |
| 670 | Orthopaedics 骨科學 | TFDA-01910 | ASTM | ASTM F2423 - 11(2020) | 2020 | Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses | 原採認標準 |
| 671 | Orthopaedics 骨科學 | TFDA-01911 | ASTM | ASTM F2624 - 12(2020) | 2020 | Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs | 原採認標準 |
| 672 | Orthopaedics | TFDA-01912 | ASTM | ASTM F1378 - | 2018 | Standard Specification for Shoulder Prostheses | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 骨科學 | | | 18e1 | | | |
| 673 | Orthopaedics 骨科學 | TFDA-01913 | ASTM | ASTM F1717 - 18 | 2018 | Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model | 原採認標準 |
| 674 | Orthopaedics 骨科學 | TFDA-01914 | ASTM | ASTM F2077 - 18 | 2018 | Test Methods For Intervertebral Body Fusion Devices | 原採認標準 |
| 675 | Orthopaedics 骨科學 | TFDA-02046 | ASTM | ASTM F2554-18 | 2018 | Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems | 原採認標準 |
| 676 | Orthopaedics 骨科學 | TFDA-02047 | ISO | ISO 14242-3:2009/A MD 1:2019 | 2019 | Implants for surgery — Wear of total hipjoint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test - First Edition | 原採認標準 |
| 677 | Orthopaedics 骨科學 | TFDA-02048 | ASTM | ASTM F2580-18 | 2018 | Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis | 原採認標準 |
| 678 | Orthopaedics 骨科學 | TFDA-02049 | ASTM | ASTM F2193 - 20 | 2020 | Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System | 原採認標準 |
| 679 | Orthopaedics 骨科學 | TFDA-02050 | ISO | ISO 14242-1:2014/A MD 1:2018 | 2018 | Implants for surgery — Wear of total hipjoint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test | 原採認標準 |
| 680 | Orthopaedics 骨科學 | TFDA-02051 | ISO | ISO 19227:2018 | 2018 | Implants for surgery - Cleanliness of orthopedic implants - General requirements - First Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 681 | Orthopaedics 骨科學 | TFDA-02052 | ASTM | ASTM F2789 - 10(2020) | 2020 | Standard Guide for Mechanical and Functional Characterization of Nucleus Devices | 原採認標準 |
| 682 | Orthopaedics 骨科學 | TFDA-02053 | ASTM | ASTM F2009 - 20 | 2020 | Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses | 原採認標準 |
| 683 | Orthopaedics 骨科學 | TFDA-02054 | ASTM | ASTM F2381 - 19 | 2019 | Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy | 原採認標準 |
| 684 | Orthopaedics 骨科學 | TFDA-02055 | ASTM | ASTM F2943 - 14(2019) | 2019 | Standard Guide for Presentation of End User Labeling Information for Orthopedic Implants Used in Joint Arthroplasty. | 原採認標準 |
| 685 | Orthopaedics 骨科學 | TFDA-02056 | ASTM | ASTM F1357 - 14(2019) | 2019 | Standard Specification for Articulating Total Wrist Implants | 原採認標準 |
| 686 | Orthopaedics 骨科學 | TFDA-02057 | ASTM | ASTM F1611 - 20 | 2020 | Standard Specification for Intramedullary Reamers | 原採認標準 |
| 687 | Orthopaedics 骨科學 | TFDA-02058 | ASTM | ASTM F2385 - 15(2019) | 2019 | Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs | 原採認標準 |
| 688 | Orthopaedics 骨科學 | TFDA-02059 | ISO | ISO 14243-3:2014/A MD 1:2020 | 2020 | Implants for surgery - Wear of total knee-joint prostheses - Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | environmental conditions for test - Second Edition | |
| 689 | Orthopaedics 骨科學 | TFDA-02060 | ASTM | ASTM E399 - 20a | 2020 | Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness of Metallic Materials | 原採認標準 |
| 690 | Orthopaedics 骨科學 | TFDA-02167 | ISO | ISO 15142-2:2003 | 2003 | Implants for surgery - Metal intramedullary nailing systems - Part 2: Locking components | 110 年度新增 採認標準 |
| 691 | Orthopaedics 骨科學 | TFDA-02168 | ISO | ISO 15142-1:2003 | 2003 | Implants for surgery — Metal intramedullary nailing systems — Part 1: Intramedullary nails | 110 年度新增 採認標準 |
| 692 | Orthopaedics 骨科學 | TFDA-02169 | ASTM | ASTM F1264 - 16e1 | 2016 | Standard Specification and Test Methods for Intramedullary Fixation Devices | 110 年度新增 採認標準 |
| 693 | Orthopaedics 骨科學 | TFDA-02170 | ASTM | ASTM F543-17 | 2017 | Standard Specification and Test Methods for Metallic Medical Bone Screws | 110 年度新增 採認標準 |
| 694 | Orthopaedics 骨科學 | TFDA-02171 | ASTM | F897-19 | 2019 | Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws | 110 年度新增 採認標準 |
| 695 | Orthopaedics 骨科學 | TFDA-02172 | ASTM | F1800-19 e1 | 2019 | Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements | 110 年度新增 採認標準 |
| 696 | Orthopaedics 骨科學 | TFDA-02173 | ASTM | F3334-19 | 2019 | Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components | 110 年度新增 採認標準 |
| 697 | Orthopaedics 骨科學 | TFDA-02174 | ASTM | F3292-19 | 2019 | Standard Practice for Inspection of Spinal Implants Undergoing Testing | 110 年度新增 採認標準 |
| 698 | Orthopaedics 骨科學 | TFDA-02175 | ASTM | ASTM F382-17 | 2017 | Standard Specification and Test Method for Metallic Bone Plates | 110 年度新增 採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 699 | Orthopaedics 骨科學 | TFDA-02176 | ASTM | ASTM F564-17 | 2017 | Standard specification and test methods for metallic bone staples | 110 年度新增採認標準 |
| 700 | Orthopaedics 骨科學 | TFDA-02177 | ASTM | ASTM F3143-20 | 2020 | Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings under Standard Conditions Using a Reciprocal Friction Simulator | 110 年度新增採認標準 |
| 701 | Orthopaedics 骨科學 | TFDA-02178 | ASTM | ASTM F3446-20 | 2020 | Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator | 110 年度新增採認標準 |
| 702 | Orthopaedics 骨科學 | TFDA-02179 | ASTM | ASTM F1223-20 | 2020 | Standard Test Method for Determination of Total Knee Replacement Constraint | 110 年度新增採認標準 |
| 703 | Orthopaedics 骨科學 | TFDA-02180 | ISO | ISO 14879-1 Second edition 2020-07 | 2020 | Implants for surgery - Total knee-joint prostheses - Part 1: Determination of endurance properties of knee tibial trays | 110 年度新增採認標準 |
| 704 | Orthopaedics 骨科學 | TFDA-02181 | ASTM | ASTM F3090-20 | 2020 | Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement | 110 年度新增採認標準 |
| 705 | Orthopaedics 骨科學 | TFDA-02182 | ASTM | ASTM F2033-20 | 2020 | Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic Ceramic and Polymeric Materials | 110 年度新增採認標準 |
| 706 | Physical Medicine 物 理醫學科學 | TFDA-00157 | ISO | ISO 7176-7:1998 | 1998 | Wheelchairs -- Part 7: Measurement of seating and wheel dimensions | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 707 | Physical Medicine 物 理醫學科學 | TFDA-00162 | ISO | ISO 7176-13:1989 | 1989 | Wheelchairs - Part 13: Determination of Coefficient of Friction of Test Surfaces | 原採認標準 |
| 708 | Physical Medicine 物 理醫學科學 | TFDA-00164 | ISO | ISO 7176-15:1996 | 1996 | Wheelchairs - Part 15: Requirements for Information Disclosure, Documentation and Labelling | 原採認標準 |
| 709 | Physical Medicine 物 理醫學科學 | TFDA-00792 | CNS | CNS 15037-1 | 2006 | 雙臂操作步行輔具－要求及測試法－第 1 部：助行器 | 原採認標準 |
| 710 | Physical Medicine 物 理醫學科學 | TFDA-00793 | CNS | CNS 15037-2 | 2006 | 雙臂操作步行輔具－要求及測試法－第 2 部：帶輪助行器 | 原採認標準 |
| 711 | Physical Medicine 物 理醫學科學 | TFDA-00794 | CNS | CNS 15037-3 | 2006 | 雙臂操作步行輔具－要求及測試法－第 3 部：附前臂支撐桌助行器 | 原採認標準 |
| 712 | Physical Medicine 物 理醫學科學 | TFDA-00795 | CNS | CNS 15024-4 | 2006 | 單臂操作之步行輔具－要求與測試方法－第 4 部：三腳或多腳步行手杖 | 原採認標準 |
| 713 | Physical Medicine 物 理醫學科學 | TFDA-00796 | CNS | CNS 14103-1 | 2009 | 義肢學與矯具學－詞彙－第 1 部：外用義肢與外用矯具之一般術語 | 原採認標準 |
| 714 | Physical Medicine 物 理醫學科學 | TFDA-00797 | CNS | CNS 14103-2 | 2009 | 義肢學與矯具學－詞彙－第 2 部：外用義肢與其穿戴者之術語 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 715 | Physical Medicine 物 理醫學科學 | TFDA-00798 | CNS | CNS 14103-3 | 2009 | 義肢學與矯具學－詞彙－第 3 部：外用矯具之術語 | 原採認標準 |
| 716 | Physical Medicine 物 理醫學科學 | TFDA-00799 | CNS | CNS 14104-1 | 2009 | 義肢學與矯具學－肢體缺陷－第 1 部：先天性肢體缺陷之描述 | 原採認標準 |
| 717 | Physical Medicine 物 理醫學科學 | TFDA-00800 | CNS | CNS 14104-2 | 2009 | 義肢學與矯具學－肢體缺陷－第 2 部：下肢截肢之描述 | 原採認標準 |
| 718 | Physical Medicine 物 理醫學科學 | TFDA-00801 | CNS | CNS 14104-3 | 2009 | 義肢學與矯具學－肢體缺陷－第 3 部：上肢截肢之描述 | 原採認標準 |
| 719 | Physical Medicine 物 理醫學科學 | TFDA-00802 | CNS | CNS 14104-4 | 2009 | 義肢學與矯具學－肢體缺陷－第 4 部：導致截肢原因之描述 | 原採認標準 |
| 720 | Physical Medicine 物 理醫學科學 | TFDA-00803 | CNS | CNS 14104-5 | 2009 | 義肢學與矯具學－肢體缺陷－第 5 部：截肢病患臨床狀態之描述 | 原採認標準 |
| 721 | Physical Medicine 物 理醫學科學 | TFDA-00804 | CNS | CNS 15265-1 | 2009 | 義肢學與矯具學－義肢組件之分類與描述－第 1 部：義肢組件之分類 | 原採認標準 |
| 722 | Physical Medicine 物 理醫學科學 | TFDA-00805 | CNS | CNS 15265-2 | 2009 | 義肢學與矯具學－義肢組件之分類與描述－第 2 部：下肢義肢組件之描述 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 723 | Physical Medicine 物 理醫學科學 | TFDA-00806 | CNS | CNS 15265-3 | 2009 | 義肢學與矯具學－義肢組件之分類與描述－第 3 部：上肢義肢組件之描述 | 原採認標準 |
| 724 | Physical Medicine 物 理醫學科學 | TFDA-00807 | CNS | CNS 15266 | 2009 | 義肢學－腕關節結構之測試方法 | 原採認標準 |
| 725 | Physical Medicine 物 理醫學科學 | TFDA-00808 | CNS | CNS 15268 | 2009 | 外用義肢與外用矯具－要求與測試方法 | 原採認標準 |
| 726 | Physical Medicine 物 理醫學科學 | TFDA-00809 | CNS | CNS 15269 | 2009 | 義肢學－下肢義肢結構測試－要求與測試方法 | 原採認標準 |
| 727 | Physical Medicine 物 理醫學科學 | TFDA-00810 | CNS | CNS 14964 | 2007 | 輪椅－應用指導綱要 | 原採認標準 |
| 728 | Physical Medicine 物 理醫學科學 | TFDA-00811 | CNS | CNS 14964-1 | 2017 | 輪椅－第 1 部：靜態穩定性之測定 | 原採認標準 |
| 729 | Physical Medicine 物 理醫學科學 | TFDA-00812 | CNS | CNS 14964-2 | 2007 | 輪椅－第 2 部：動態穩定性之測定 | 原採認標準 |
| 730 | Physical Medicine 物 理醫學科學 | TFDA-00814 | CNS | CNS 14964-4 | 2017 | 輪椅－第 4 部：電動輪椅及代步車之耗能－理論 行駛距離之測定 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 731 | Physical Medicine 物 理醫學科學 | TFDA-00815 | CNS | CNS 14964-6 | 2005 | 輪椅－第 6 部：電動輪椅最大速度、加速度與減速度之測定 | 原採認標準 |
| 732 | Physical Medicine 物 理醫學科學 | TFDA-00816 | CNS | CNS 14964-7 | 2006 | 輪椅－第 7 部：座椅及輪子尺度之量測 | 原採認標準 |
| 733 | Physical Medicine 物 理醫學科學 | TFDA-00817 | CNS | CNS 14964-8 | 2018 | 輪椅－第 8 部：輪椅靜力、衝擊與疲勞強度測試方法與要求 | 原採認標準 |
| 734 | Physical Medicine 物 理醫學科學 | TFDA-00819 | CNS | CNS 14964-10 | 2017 | 輪椅－第 10 部：電動輪椅越障能力試驗 | 原採認標準 |
| 735 | Physical Medicine 物 理醫學科學 | TFDA-00821 | CNS | CNS 14964-13 | 2006 | 輪椅－第 13 部：測試表面摩擦係數之測定 | 原採認標準 |
| 736 | Physical Medicine 物 理醫學科學 | TFDA-00822 | CNS | CNS 14964-14 | 2005 | 輪椅－第 14 部：電動輪椅之電力與控制系統測試方法與要求 | 原採認標準 |
| 737 | Physical Medicine 物 理醫學科學 | TFDA-00823 | CNS | CNS 14964-15 | 2007 | 輪椅－第 15 部：資訊宣告、文件與標示之要求 | 原採認標準 |
| 738 | Physical Medicine 物 理醫學科學 | TFDA-00825 | CNS | CNS 14964-19 | 2013 | 輪椅－第 19 部：機動車輛使用之輪型移動裝置 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 739 | Physical Medicine 物 理醫學科學 | TFDA-00826 | CNS | CNS 14964-21 | 2019 | 輪椅－第 21 部：電動輪椅及電動代步車之電磁 相容性要求和測試方法 | 原採認標準 |
| 740 | Physical Medicine 物 理醫學科學 | TFDA-00827 | CNS | CNS 14964-22 | 2007 | 輪椅－第 22 部：設定程序 | 原採認標準 |
| 741 | Physical Medicine 物 理醫學科學 | TFDA-00935 | ISO | ISO 7176-4:2008 | 2008 | Wheelchairs -- Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range | 原採認標準 |
| 742 | Physical Medicine 物 理醫學科學 | TFDA-00936 | ISO | ISO 7176-5:2008 | 2008 | Wheelchairs -- Part 5: Determination of dimensions, mass and manoeuvring space | 原採認標準 |
| 743 | Physical Medicine 物 理醫學科學 | TFDA-00937 | ISO | ISO 7176-9:2009 | 2009 | Wheelchairs -- Part 9: Climatic tests for electric wheelchairs | 原採認標準 |
| 744 | Physical Medicine 物 理醫學科學 | TFDA-00938 | ISO | ISO 7176-10:2008 | 2008 | Wheelchairs -- Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs | 原採認標準 |
| 745 | Physical Medicine 物 理醫學科學 | TFDA-00939 | ISO | ISO 7176-14:2008 | 2008 | Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods | 原採認標準 |
| 746 | Physical Medicine 物 理醫學科學 | TFDA-00940 | ISO | ISO 7176-21:2009 | 2009 | Wheelchairs -- Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | battery chargers | |
| 747 | Physical Medicine 物 理醫學科學 | TFDA-01383 | CNS | CNS 15469-1 | 2011 | 步行輔具杖端－要求與試驗方法－第 1 部：杖端 摩擦力 (Tips for assistive products for walking - Requirements and test methods - Part 1: Friction of tips) (IDT: ISO 24415-1:2009) | 原採認標準 |
| 748 | Physical Medicine 物 理醫學科學 | TFDA-01384 | CNS | CNS 15469-2 | 2013 | 步行輔具杖端－要求與試驗方法－第 2 部：拐杖 杖端耐用性 Tips for assistive products for walking － Requirements and test methods – Part 2: Durability of tips for crutches (IDT: ISO 24415-2:2011) | 原採認標準 |
| 749 | Physical Medicine 物 理醫學科學 | TFDA-01385 | ISO | ISO 7176-11:2012 | 2012 | Wheelchairs -- Part 11: Test dummies | 原採認標準 |
| 750 | Physical Medicine 物 理醫學科學 | TFDA-01386 | ISO | ISO 16840-10:2021 | 2021 | Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method | 原採認標準 |
| 751 | Physical Medicine 物 理醫學科學 | TFDA-01387 | ISO | ISO 7176-3:2012 | 2012 | Wheelchairs -- Part 3: Determination of effectiveness of brakes | 原採認標準 |
| 752 | Physical Medicine 物 理醫學科學 | TFDA-01388 | CNS | CNS 15677-1 | 2013 | 失能者或生理障礙者之技術系統和輔具－ 輪椅 束縛裝置和乘坐者安全拘束系統－ 第 1 部：全 部系統之要求及測試方法 (Technical systems and aids for disabled or handicapped persons – Wheelchair tiedown and occupant-restraint systems | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | - Part 1: Requirements and test methods for all systems) | |
| 753 | Physical Medicine 物 理醫學科學 | TFDA-01642 | CNS | CNS 14964-16 | 2014 | 輪椅－第 16 部：姿勢支撐裝置之耐燃性 (Wheelchairs – Part 16: Resistance to ignition of postural support devices) | 原採認標準 |
| 754 | Physical Medicine 物 理醫學科學 | TFDA-01643 | CNS | CNS 14964-25 | 2014 | 輪椅－第 25 部：電動輪椅之電池組及充電器 (Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs) | 原採認標準 |
| 755 | Physical Medicine 物 理醫學科學 | TFDA-01645 | CNS | CNS 14964-3 | 2015 | 輪椅－第 3 部：煞車有效性之測定 | 原採認標準 |
| 756 | Physical Medicine 物 理醫學科學 | TFDA-01646 | CNS | CNS 14964-5 | 2017 | 輪椅－第 5 部：尺度、質量及操控空間之測定 | 原採認標準 |
| 757 | Physical Medicine 物 理醫學科學 | TFDA-01647 | CNS | CNS 14964-9 | 2014 | 輪椅－第 9 部：電動輪椅之耐候試驗 (Wheelchairs – Part 9: Climatic tests for electric wheelchairs) | 原採認標準 |
| 758 | Physical Medicine 物 理醫學科學 | TFDA-01648 | CNS | CNS 15191 | 2012 | 木手杖 | 原採認標準 |
| 759 | Physical Medicine 物 理醫學科學 | TFDA-01649 | CNS | CNS 15192 | 2013 | 非木質手杖 | 原採認標準 |
| 760 | Physical | TFDA-01650 | CNS | CNS 15628-4 | 2015 | 輪椅乘坐系統－第 4 部：作為機動車輛之乘坐系 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | Medicine 物理醫學科學 | | | | | 統(Wheelchair seating – Part 4: Seating systems for use in motor vehicles) | |
| 761 | Physical Medicine 物理醫學科學 | TFDA-01652 | CNS | CNS 15910-1 | 2016 | 家用之褥瘡防止鋪墊—第 1 部：種類 | 原採認標準 |
| 762 | Physical Medicine 物理醫學科學 | TFDA-01653 | CNS | CNS 15910-2 | 2016 | 家用之褥瘡防止鋪墊—第 2 部：替換靜態型 | 原採認標準 |
| 763 | Physical Medicine 物理醫學科學 | TFDA-01654 | CNS | CNS 15910-3 | 2016 | 家用之褥瘡防止鋪墊—第 3 部：壓力交替型 | 原採認標準 |
| 764 | Physical Medicine 物理醫學科學 | TFDA-01655 | EN | EN 12183:2014 | 2014 | Manual wheelchairs - Requirements and test methods | 原採認標準 |
| 765 | Physical Medicine 物理醫學科學 | TFDA-01656 | EN | EN 12184:2014 | 2014 | Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods | 原採認標準 |
| 766 | Physical Medicine 物理醫學科學 | TFDA-01659 | ISO | ISO 7176-1:2014 | 2014 | Wheelchairs - Part 1: Determination of Static Stability | 原採認標準 |
| 767 | Physical Medicine 物理醫學科學 | TFDA-01661 | ISO | ISO 7176-22:2014 | 2014 | Wheelchairs -- Part 22: Set-up procedures | 原採認標準 |
| 768 | Physical | TFDA-01662 | ISO | ISO 7176-8:2014 | 2014 | Wheelchairs -- Part 8: Requirements and test | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | Medicine 物理醫學科學 | | | | | methods for static, impact and fatigue strengths | |
| 769 | Physical Medicine 物理醫學科學 | TFDA-01844 | CNS | CNS 16010-1 | 2017 | 尿液吸收輔具－詞彙－第 1 部：尿液失禁狀態 | 原採認標準 |
| 770 | Physical Medicine 物理醫學科學 | TFDA-01845 | CNS | CNS 16010-2 | 2017 | 尿液吸收輔具－詞彙－第 2 部：產品 | 原採認標準 |
| 771 | Physical Medicine 物理醫學科學 | TFDA-01846 | CNS | CNS 16010-3 | 2017 | 尿液吸收輔具－詞彙－第 3 部：產品型式識別 | 原採認標準 |
| 772 | Physical Medicine 物理醫學科學 | TFDA-01847 | IEC | IEC 60601-2-3:2012+AMD1:2016 CSV | 2016 | Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of shortwave therapy equipment | 原採認標準 |
| 773 | Physical Medicine 物理醫學科學 | TFDA-01848 | IEC | IEC 60601-2-6:2012+AMD1:2016 CSV | 2016 | Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment | 原採認標準 |
| 774 | Physical Medicine 物理醫學科學 | TFDA-01849 | ISO | ISO 7176-19:2008/A MD 1:2015 | 2015 | Wheelchairs Part 19: Wheeled mobility devices for use as seats in motor vehicles | 原採認標準 |
| 775 | Physical Medicine 物理醫學科學 | TFDA-01850 | ISO | ISO 7176-2:2017 | 2017 | Wheelchairs - Part 2: Determination of Dynamic Stability of Electric Wheelchairs | 原採認標準 |
| 776 | Physical | TFDA-01851 | ISO | ISO 7176-6:2018 | 2018 | Wheelchairs - Part 6: Determination of maximum | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | Medicine 物 理醫學科學 | | | | | speed, acceleration and deceleration of electric wheelchairs | |
| 777 | Physical Medicine 物 理醫學科學 | TFDA-01876 | ISO | ISO 7176-28:2012 | 2012 | Wheelchairs - Part 28: Requirements and test methods for stair-climbing devices | 原採認標準 |
| 778 | Physical Medicine 物 理醫學科學 | TFDA-02061 | CNS | CNS 14964-28 | 2016 | 輪椅－第 28 部：爬梯裝置之要求與測試方法 | 原採認標準 |
| 779 | Physical Medicine 物 理醫學科學 | TFDA-02062 | ISO | ISO 11199-2:2021 | 2021 | Assistive products for walking manipulated by both arms — Requirements and test methods — Part 2: Rollators | 原採認標準 |
| 780 | Physical Medicine 物 理醫學科學 | TFDA-02063 | CNS | CNS 16051 | 2018 | 具電動輔助起站及坐下機構之座椅與椅座 | 原採認標準 |
| 781 | Physical Medicine 物 理醫學科學 | TFDA-02064 | CNS | CNS 16077 | 2018 | 身心障礙者移位用起吊裝置－要求及試驗法 | 原採認標準 |
| 782 | Physical Medicine 物 理醫學科學 | TFDA-02183 | Japanes e Standar ds Associa tion | JIS D9301:2013 | 2013 | Bicycles For General Use | 110 年度新增 採認標準 |
| 783 | Software/Info | TFDA-00489 | CLSI | AUTO2-A2 | 2006 | Laboratory Automation: Bar Codes for Specimen | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | rmatics 軟體 /醫療資訊 | | | | | Container Identification; Approved Standard Second Edition | |
| 784 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-00588 | IEC | ISO/IEC 25062:2006 | 2006 | Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Common Industry Format (CIF) for usability test reports | 原採認標準 |
| 785 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-00644 | CLSI | AUTO8-A | 2006 | Managing and Validating Laboratory Information Systems; Approved Guideline | 原採認標準 |
| 786 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-00735 | CLSI | AUTO10-A | 2006 | Autoverification of Clinical Laboratory Test Results | 原採認標準 |
| 787 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-00852 | CLSI | AUTO03-A2 | 2009 | Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard-Second Edition | 原採認標準 |
| 788 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-00959 | IEC | IEC/TR 80002-1 ed1.0 :2009 | 2009 | Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software | 原採認標準 |
| 789 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-00961 | CNS | CNS 14232-1 | 2010 | 健康資訊交換第七層協定—第 1 部：簡介 | 原採認標準 |
| 790 | Software/Info rmatics 軟體 | TFDA-00962 | CNS | CNS 14232-4 | 2010 | 健康資訊交換第七層協定—第 4 部：醫囑 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | /醫療資訊 | | | | | | |
| 791 | Software/Informatics 軟體 /醫療資訊 | TFDA-00963 | CNS | CNS 14232-5 | 2010 | 健康資訊交換第七層協定—第 5 部：查詢 | 原採認標準 |
| 792 | Software/Informatics 軟體 /醫療資訊 | TFDA-00964 | CNS | CNS 14232-6 | 2010 | 健康資訊交換第七層協定—第 6 部：財務管理 | 原採認標準 |
| 793 | Software/Informatics 軟體 /醫療資訊 | TFDA-00965 | CNS | CNS 14232-7 | 2010 | 健康資訊交換第七層協定—第 7 部：觀察報告 | 原採認標準 |
| 794 | Software/Informatics 軟體 /醫療資訊 | TFDA-00966 | CNS | CNS 14232-8 | 2010 | 健康資訊交換第七層協定—第 8 部：公用主檔 | 原採認標準 |
| 795 | Software/Informatics 軟體 /醫療資訊 | TFDA-00967 | CNS | CNS 14232-9 | 2010 | 健康資訊交換第七層協定—第 9 部：醫療紀錄/ 資訊管理 | 原採認標準 |
| 796 | Software/Informatics 軟體 /醫療資訊 | TFDA-00968 | CNS | CNS 14232-10 | 2010 | 健康資訊交換第七層協定—第 10 部：排程 | 原採認標準 |
| 797 | Software/Informatics 軟體 /醫療資訊 | TFDA-00969 | CNS | CNS 14232-11 | 2010 | 健康資訊交換第七層協定—第 11 部：病患轉診 | 原採認標準 |
| 798 | Software/Informatics 軟體 | TFDA-00970 | CNS | CNS 14232-12 | 2010 | 健康資訊交換第七層協定—第 12 部：病患照護 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | /醫療資訊 | | | | | | |
| 799 | Software/Informatics 軟體 /醫療資訊 | TFDA-00971 | CNS | CNS 14232-13 | 2010 | 健康資訊交換第七層協定－第 13 部：臨床實驗室自動化 | 原採認標準 |
| 800 | Software/Informatics 軟體 /醫療資訊 | TFDA-00972 | CNS | CNS 14232-14 | 2010 | 健康資訊交換第七層協定－第 14 部：應用管理 | 原採認標準 |
| 801 | Software/Informatics 軟體 /醫療資訊 | TFDA-00973 | CNS | CNS 14232-15 | 2010 | 健康資訊交換第七層協定－第 15 部：人事管理 | 原採認標準 |
| 802 | Software/Informatics 軟體 /醫療資訊 | TFDA-01054 | AAMI | AAMI TIR80001-2-1:2012 | 2012 | Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples | 原採認標準 |
| 803 | Software/Informatics 軟體 /醫療資訊 | TFDA-01055 | AAMI | AAMI TIR80001-2-2:2012 | 2012 | Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls | 原採認標準 |
| 804 | Software/Informatics 軟體 /醫療資訊 | TFDA-01056 | AAMI | AAMI TIR80001-2-3:2012 | 2012 | Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for Wireless Networks | 原採認標準 |
| 805 | Software/Informatics 軟體 /醫療資訊 | TFDA-01057 | AAMI | AAMI TIR80001-2-4:2012 | 2012 | Application of risk management for IT-networks incorporating medical devices — Part 2-4: General implementation guidance for healthcare delivery | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | organizations | |
| 806 | Software/Informatics 軟體 /醫療資訊 | TFDA-01059 | CNS | CNS 14232-16 | 2010 | 健康資訊交換第七層協定－第 16 部：附錄 (Health Level Seven (HL7) - Part 16: Appendix) | 原採認標準 |
| 807 | Software/Informatics 軟體 /醫療資訊 | TFDA-01060 | CNS | CNS 14232-2 | 2010 | 健康資訊交換第七層協定－第 2 部：控制 (Health Level Seven (HL7) - Part 2: Control) | 原採認標準 |
| 808 | Software/Informatics 軟體 /醫療資訊 | TFDA-01061 | CNS | CNS 14232-3 | 2010 | 健康資訊交換第七層協定－第 3 部：病患管理 (Health Level Seven (HL7) - Part 3: Patient administration) | 原採認標準 |
| 809 | Software/Informatics 軟體 /醫療資訊 | TFDA-01062 | IEC | IEC 62443-2-1 ed1.0 | 2010 | Industrial communication networks—Network and system security—Part 2–1: Establishing an industrial automation and control system security program. | 原採認標準 |
| 810 | Software/Informatics 軟體 /醫療資訊 | TFDA-01063 | IEC | IEC 80001-1:2010 | 2010 | Application of risk management for IT Networks incorporating medical devices — Part 1: Roles, responsibilities and activities | 原採認標準 |
| 811 | Software/Informatics 軟體 /醫療資訊 | TFDA-01064 | IEC | IEC/TR 80002-1:2009 | 2009 | Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software - Edition 1.0 | 原採認標準 |
| 812 | Software/Informatics 軟體 /醫療資訊 | TFDA-01065 | IEC | IEC/TR 62443-3-1 ed1.0 | 2009 | Industrial communication networks—Network and system security—Part 3–1: Security technologies for industrial automation and control systems. | 原採認標準 |
| 813 | Software/Info | TFDA-01067 | IEC | IEC/TS | 2009 | Industrial communication networks—Network and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | rmatics 軟體 /醫療資訊 | | | 62443-1-1 ed1.0 | | system security—Part 1–1: Terminology,concepts and models | |
| 814 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01069 | ISO | ISO/IEC/IEEE 15026-4:2021 | 2021 | Systems and software engineering — Systems and software assurance — Part 4: Assurance in the life cycle | 原採認標準 |
| 815 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01070 | ISO | ISO/IEC 25001:2014 | 2014 | Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Planning and management - Second Edition | 原採認標準 |
| 816 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01071 | ISO | ISO/IEC 25051:2014 | 2014 | Software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing - Second Edition | 原採認標準 |
| 817 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01074 | ISO | ISO/IEEE 11073-10404:2010 | 2010 | Health informatics Personal health device communication Part 10404: Device specialization Pulse oximeter | 原採認標準 |
| 818 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01075 | ISO | ISO/IEEE 11073-10406:2012 | 2011 | Health informatics--Personal health device communication Part 10406: Device specialization--Basic electrocardiograph (ECG) (1-to 3-lead ECG) | 原採認標準 |
| 819 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01076 | ISO | ISO/IEEE 11073-10407:2010 | 2010 | ISO/IEEE Health informatics Personal health device communication Part 10407: Device specialization Blood pressure monitor | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 820 | Software/Informatics 軟體 /醫療資訊 | TFDA-01077 | ISO | ISO/IEEE 11073-10408:2010 | 2010 | Health Informatics-Personal Health Device Communication Part 10408: Device Specialization-Thermometer | 原採認標準 |
| 821 | Software/Informatics 軟體 /醫療資訊 | TFDA-01078 | ISO | ISO/IEEE 11073-10415:2010 | 2010 | Health Informatics-Personal Health Device Communication Part 10415: Device Specialization-Weighing Scale | 原採認標準 |
| 822 | Software/Informatics 軟體 /醫療資訊 | TFDA-01082 | ISO | ISO/IEEE 11073-10472:2012 | 2012 | Health Informatics—Personal health device communication—Part 10472 Device specialization—Medication monitor | 原採認標準 |
| 823 | Software/Informatics 軟體 /醫療資訊 | TFDA-01083 | ISO | ISO/IEEE 11073-20101:2004 | 2004 | IEEE Standard for Health Informatics - Point-Of-Care Medical Device Communication - Part 20101: Application Profile - Base Standard | 原採認標準 |
| 824 | Software/Informatics 軟體 /醫療資訊 | TFDA-01664 | IEC | IEC 62304:2006+AMD 1:2015 | 2015 | Medical device software - Software life cycle processes | 原採認標準 |
| 825 | Software/Informatics 軟體 /醫療資訊 | TFDA-01665 | IEC | IEC 82304-1:2016 | 2016 | Health software - Part 1: General requirements for product safety - Edition 1.0 | 原採認標準 |
| 826 | Software/Informatics 軟體 /醫療資訊 | TFDA-01666 | IEC | IEC/TR 80001-2-5:2014 | 2014 | Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems - Edition 1.0 | 原採認標準 |
| 827 | Software/Informatics 軟體 | TFDA-01667 | IEC | IEC/TR 80002-3:2014 | 2014 | Medical device software –Part 3: Process reference model of medical device software life cycle | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | /醫療資訊 | | | | | processes (IEC 62304) | |
| 828 | Software/Informatics 軟體 /醫療資訊 | TFDA-01668 | IEEE | IEEE Std 11073-10417-2015 | 2015 | Health Informatics-Personal health device communication Part 10417: Device specialization-Glucose meter | 原採認標準 |
| 829 | Software/Informatics 軟體 /醫療資訊 | TFDA-01669 | IEEE | IEEE Std 11073-10422-2016 | 2016 | Health informatics-Personal health device communication Part 10422: Device specialization - Urine analyzer | 原採認標準 |
| 830 | Software/Informatics 軟體 /醫療資訊 | TFDA-01670 | IEEE | IEEE Std 11073-10424-2014/Cor 1-2017 | 2017 | Health informatics—Personal health device communication Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE) | 原採認標準 |
| 831 | Software/Informatics 軟體 /醫療資訊 | TFDA-01674 | IEEE | IEEE Std 3333.2.1-2015 | 2015 | IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling | 原採認標準 |
| 832 | Software/Informatics 軟體 /醫療資訊 | TFDA-01675 | ISO | ISO/TR 80001-2-6:2014 | 2014 | Application of risk management for IT-networks incorporating medical devices — Part 2-6: Application guidance — Guidance for responsibility agreements | 原採認標準 |
| 833 | Software/Informatics 軟體 /醫療資訊 | TFDA-01676 | ISO | ISO/TR 80002-2:2017 | 2017 | Medical device software - Part 2: Validation of software for medical device quality systems | 原採認標準 |
| 834 | Software/Informatics 軟體 /醫療資訊 | TFDA-01677 | ISO | ISO/IEEE 11073-10102:2014 | 2014 | Health informatics—Personal health device communication Part 10102: Nomenclature—Annotated ECG | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 835 | Software/Informatics 軟體 /醫療資訊 | TFDA-01679 | ISO | ISO/IEEE 11073-10421:2012 | 2012 | Health informatics—Personal health device communication Part 10421: Device specialization—Peak expiratory flow monitor (peak flow) | 原採認標準 |
| 836 | Software/Informatics 軟體 /醫療資訊 | TFDA-01852 | IEEE | IEEE 1012-2016/COR 1-2017 | 2017 | IEEE Standard for System and Software Verification and Validation | 原採認標準 |
| 837 | Software/Informatics 軟體 /醫療資訊 | TFDA-01854 | IEEE | IEEE 11073-10425:2017 | 2017 | Health informatics—Personal health device communication Part 10425: Device Specialization—Continuous Glucose Monitor (CGM) | 原採認標準 |
| 838 | Software/Informatics 軟體 /醫療資訊 | TFDA-01855 | IEEE | IEEE 11073-20601:2016 | 2016 | Health informatics--Personal health device communication Part 20601: Application profile-Optimized Exchange Protocol. | 原採認標準 |
| 839 | Software/Informatics 軟體 /醫療資訊 | TFDA-01856 | IEEE | IEEE/IEC/ISO 12207:2017 | 2017 | Systems and software engineering -- Software life cycle processes | 原採認標準 |
| 840 | Software/Informatics 軟體 /醫療資訊 | TFDA-01857 | ISO | ISO/IEEE 11073-10102:2014 | 2014 | Health informatics -- Point-of-care medical device communication Part 10102: Nomenclature --Annotated ECG | 原採認標準 |
| 841 | Software/Informatics 軟體 /醫療資訊 | TFDA-01858 | ISO | ISO/IEEE 11073-10417:2017 | 2017 | IEEE Health informatics -- Personal health device communication Part 10417: Device Specialization -- Glucose Meter | 原採認標準 |
| 842 | Software/Info | TFDA-01915 | AAMI | AAMI | 2018 | Guidance on the use of AGILE practices in the | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | rmatics 軟體 /醫療資訊 | | | TIR45:2012/(R)2 018 | | development of medical device software | |
| 843 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01916 | ASTM | ASTM F2761-09(2013) | 2013 | Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model | 原採認標準 |
| 844 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-01917 | ISO | ISO/IEEE 11073-10418:201 4/COR 1:2016 | 2016 | Health informatics—Personal health device communication—Part 10418 Device specialization—International normalized ratio (INR) monitor | 原採認標準 |
| 845 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-02065 | ISO | ISO/IEEE 11073-10101:202 0 | 2020 | Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature | 原採認標準 |
| 846 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-02066 | IEEE | IEEE Std 11073-10207-201 7 | 2017 | Health informatics—Point-of-care medical device communication Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication. | 原採認標準 |
| 847 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-02067 | ISO | ISO/IEEE 11073-20702:201 8 | 2018 | Health informatics—Point-of-care medical device communication—Part 20702: Medical devices communication profile for web services | 原採認標準 |
| 848 | Software/Info rmatics 軟體 /醫療資訊 | TFDA-02068 | ISO | ISO/IEEE 11073-10201:202 0 | 2020 | ISO/IEEE Health Informatics - Point-Of-Care Medical Device Communication - Part 10201: Domain Information Model | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 849 | Software/Informatics 軟體 / 醫療資訊 | TFDA-02069 | AAMI | AAMI TIR57:2016/(R)2019 | 2019 | Principles for medical device security—Risk management | 原採認標準 |
| 850 | Software/Informatics 軟體 / 醫療資訊 | TFDA-02184 | ISO/IEC | ISO/IEC 27035-1:2016 | 2016 | Information technology — Security techniques — Information security incident management — Part 1: Principles of incident management | 110 年度新增採認標準 |
| 851 | Software/Informatics 軟體 / 醫療資訊 | TFDA-02185 | ISO/IEC | ISO/IEC 27035-2:2016 | 2016 | Information technology — Security techniques — Information security incident management — Part 2: Guidelines to plan and prepare for incident response | 110 年度新增採認標準 |
| 852 | Software/Informatics 軟體 / 醫療資訊 | TFDA-02186 | AAMI | AAMI TIR 97:2019 | 2019 | Principles for medical device security—Postmarket risk management for device manufacturers | 110 年度新增採認標準 |
| 853 | Software/Informatics 軟體 / 醫療資訊 | TFDA-02187 | ISO/IEC | ISO/IEC 27000 | 2018 | Information security management systems | 110 年度新增採認標準 |
| 854 | Software/Informatics 軟體 / 醫療資訊 | TFDA-02188 | IEC | IEC TR 80001-2-8:2016 | 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 | 110 年度新增採認標準 |
| 855 | Software/Informatics 軟體 / 醫療資訊 | TFDA-02189 | ANSI UL | ANSI UL 2900-1:2017 | 2017 | Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements | 110 年度新增採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 856 | Software/Informatics 軟體/醫療資訊 | TFDA-02190 | ANSI UL | ANSI UL 2900-2-1:2017 | 2017 | Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems | 110 年度新增採認標準 |
| 857 | Software/Informatics 軟體/醫療資訊 | TFDA-02191 | IEEE | IEEE Std 11073-40102:2020 | 2020 | Health informatics - Device interoperability. Part 40102: Foundational - Cybersecurity - Capabilities for mitigation. | 110 年度新增採認標準 |
| 858 | Software/Informatics 軟體/醫療資訊 | TFDA-02192 | IEEE | IEEE Std 11073-40101:2020 | 2020 | Health informatics - Device interoperability Part 40101: Foundational - Cybersecurity - Processes for vulnerability assessment. | 110 年度新增採認標準 |
| 859 | Radiology 放射學科學 | TFDA-00282 | ISO | ISO 12005:2003 | 2003 | Lasers and laser-related equipment - Test methods for laser beam parameters - Polarization | 原採認標準 |
| 860 | Radiology 放射學科學 | TFDA-00283 | ISO | ISO 13696:2002 | 2004 | Optics and optical instruments -- Test methods for radiation scattered by optical components | 原採認標準 |
| 861 | Radiology 放射學科學 | TFDA-00412 | IEC | IEC 61847: 1998 | 1998 | Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics Ed. 1.0 | 原採認標準 |
| 862 | Radiology 放射學科學 | TFDA-00414 | ISO | ISO 11146-2:2021 | 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 |
| 863 | Radiology 放射學科學 | TFDA-00415 | ISO | ISO/TR 11146-3:2004/Cor 1:2005 | 2005 | Lasers and laser-related equipment -- Test methods for laser beam widths, divergence angles and beam propagation ratios -- Part 3: Intrinsic and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | geometrical laser beam classification, propagation and details of test methods | |
| 864 | Radiology 放射學科學 | TFDA-00417 | ISO | ISO 9236-1:2004 | 2004 | Photography - Sensitometry of screen/film systems for medical radiography - Part 1: Determination of sensitometric curve shape, speed and average gradient | 原採認標準 |
| 865 | Radiology 放射學科學 | TFDA-00418 | ISO | ISO 4090:2001 | 2001 | Photography - Medical radiographic cassette/screens/films and hard-copy imaging films - Dimensions and specifications | 原採認標準 |
| 866 | Radiology 放射學科學 | TFDA-00419 | ISO | ISO 5799:1991 | 1991 | Photography -- Direct-exposing medical and dental radiographic film/process systems -- Determination of ISO speed and ISO average gradient | 原採認標準 |
| 867 | Radiology 放射學科學 | TFDA-00421 | ISO | ISO 15367-1:2003 | 2003 | Lasers and laser-related equipment -- Test methods for determination of the shape of a laser beam wavefront -- Part 1: Terminology and fundamental aspects | 原採認標準 |
| 868 | Radiology 放射學科學 | TFDA-00422 | ISO | ISO 15367-2:2005 | 2005 | Lasers and laser-related equipment - Test methods for determination of the shape of a laser beam wavefront - Part 2: Shack-Hartman sensors | 原採認標準 |
| 869 | Radiology 放射學科學 | TFDA-00431 | IEC | IEC/TR 60825-14 - Ed. 1.0 | 2004 | Safety of laser products - Part 14: A user's guide | 原採認標準 |
| 870 | Radiology 放射學科學 | TFDA-00584 | IEC | IEC/TR 60825-8:2006 | 2006 | Safety of laser products - Part 8: Guidelines for the safe use of laser beams on humans | 原採認標準 |
| 871 | Radiology | TFDA-00730 | IEC | IEC | 2008 | Medical electrical equipment - Part 2-29: Particular | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 放射學科學 | | | 60601-2-29:2008 Edition 3.0 | | requirements for the basic safety and essential performance of radiotherapy simulators | |
| 872 | Radiology 放射學科學 | TFDA-00731 | ISO | ISO 11670:2003/Cor1: 2004 | 2004 | Lasers and laser-related equipment -- Test methods for laser beam parameters -- Beam positional stability | 原採認標準 |
| 873 | Radiology 放射學科學 | TFDA-00747 | CNS | CNS 15211 | 2010 | 健康資訊學－醫學數位影像及通信暨工作流程及資料處理 | 原採認標準 |
| 874 | Radiology 放射學科學 | TFDA-00896 | IEC | IEC 60601-2-5:2009 ed3.0 | 2009 | Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment | 原採認標準 |
| 875 | Radiology 放射學科學 | TFDA-00898 | IEC | IEC/TR 60825-3:2008 ed2.0 | 2008 | Safety of laser products - Part 3: Guidance for laser displays and shows | 原採認標準 |
| 876 | Radiology 放射學科學 | TFDA-00974 | IEC | IEC 60976:2007 ed2.0 | 2007 | Medical electrical equipment - Medical electron accelerators - Functional performance characteristics | 原採認標準 |
| 877 | Radiology 放射學科學 | TFDA-01245 | ISO | ISO 21254-3:2011 | 2011 | Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Part 3: Assurance of laser power (energy) handling capabilities - First Edition | 原採認標準 |
| 878 | Radiology 放射學科學 | TFDA-01247 | ISO | ISO TR 21254-4:2011 | 2011 | Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Part 4: Inspection, detection and measurement - First Edition | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 879 | Radiology 放射學科學 | TFDA-01390 | CNS | CNS 15584 | 2013 | X 射線管組件之永久過濾測定 (Determination of the permanent filtration of X-ray tube assemblies (IDT: IEC 60522:1999)) | 原採認標準 |
| 880 | Radiology 放射學科學 | TFDA-01392 | CNS | CNS 15586 | 2013 | 醫電設備電性安全－醫用診斷 X 射線管組件－焦斑特性 (Medical electrical equipment – X-ray tube assemblies for medical diagnosis –Characteristics of focal spots (IDT: IEC 60336:2005)) | 原採認標準 |
| 881 | Radiology 放射學科學 | TFDA-01393 | CNS | CNS 15587 | 2013 | 醫用診斷 X 射線設備－用於測定特性的輻射條件 (Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics (IDT: IEC 61267:2005)) | 原採認標準 |
| 882 | Radiology 放射學科學 | TFDA-01394 | IEC | IEC 60601-1-3:2008/ AMD2:2021 | 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 |
| 883 | Radiology 放射學科學 | TFDA-01395 | IEC | IEC 60601-2-11:2013 | 2013 | Medical electrical equipment – Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment - Edition 3.0 | 原採認標準 |
| 884 | Radiology 放射學科學 | TFDA-01404 | IEC | IEC 60627:2013 | 2013 | Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids - Edition 3.0 | 原採認標準 |
| 885 | Radiology | TFDA-01406 | IEC | IEC | 2017 | Interpretation sheet 1 - Safety of laser products - | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 放射學科學 | | | 60825-1:2014/IS H1:2017 | | Part 1: Equipment classification and requirements | |
| 886 | Radiology 放射學科學 | TFDA-01407 | IEC | IEC 60825-2:2021 | 2021 | Safety of laser products - Part 2: Safety of optical fibre communication systems (OFCSS) | 原採認標準 |
| 887 | Radiology 放射學科學 | TFDA-01408 | IEC | IEC 60825-4:2006/A MD2:2011 | 2011 | Safety of laser products – Part 4: Laser guards - Edition 2.2 | 原採認標準 |
| 888 | Radiology 放射學科學 | TFDA-01409 | IEC | IEC 61161:2013 ed3.0 | 2013 | Ultrasonics—Power measurement—Radiation force balances and performance requirements. | 原採認標準 |
| 889 | Radiology 放射學科學 | TFDA-01410 | IEC | IEC 61217:2011 | 2011 | Radiotherapy equipment – Coordinates, movements and scales - Edition 2.0 | 原採認標準 |
| 890 | Radiology 放射學科學 | TFDA-01412 | IEC | IEC 61223-3-2:2007 | 2013 | Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment - Edition 2.0 | 原採認標準 |
| 891 | Radiology 放射學科學 | TFDA-01413 | IEC | IEC 61223-3-4:2000 | 2000 | Evaluation and Routine Testing in Medical Imaging Departments - Part 3-4: Acceptance Tests - Imaging Performance of Dental X-Ray Equipment - Edition 1.0 | 原採認標準 |
| 892 | Radiology 放射學科學 | TFDA-01415 | IEC | IEC 61331-1:2014 | 2014 | Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials - Edition 2.0 | 原採認標準 |
| 893 | Radiology 放射學科學 | TFDA-01416 | IEC | IEC 61331-2:2014 | 2014 | Protective devices against diagnostic medical X-radiation – Part 2: Translucent protective plates - | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | Edition 2.0 | |
| 894 | Radiology 放射學科學 | TFDA-01417 | IEC | IEC 61331-3:2014 | 2004 | Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing, eyewear and protective patient shields - Edition 2.0 | 原採認標準 |
| 895 | Radiology 放射學科學 | TFDA-01418 | IEC | IEC 61674:2012 | 2012 | Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging - Edition 2.0 | 原採認標準 |
| 896 | Radiology 放射學科學 | TFDA-01419 | IEC | IEC 61689:2013 | 2013 | Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz - Edition 3.0 | 原採認標準 |
| 897 | Radiology 放射學科學 | TFDA-01420 | IEC | IEC 62083:2009 | 2009 | Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems | 原採認標準 |
| 898 | Radiology 放射學科學 | TFDA-01421 | IEC | IEC 62127-1:2007/A MD1:2013 | 2013 | Ultrasonics—Hydrophones—Part 1: Measurement and characterization of medical ultrasonic fields up to 40 megahertz (MHz). | 原採認標準 |
| 899 | Radiology 放射學科學 | TFDA-01423 | IEC | IEC 62127-3:2007+A MD1:2013 | 2013 | Ultrasonics—Hydrophones—Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz. | 原採認標準 |
| 900 | Radiology 放射學科學 | TFDA-01424 | IEC | IEC 62555:2013 ed1.0 | 2013 | Ultrasonics—Power measurement—High intensity therapeutic ultrasound (HITU) transducers and systems | 原採認標準 |
| 901 | Radiology 放射學科學 | TFDA-01426 | IEEE | IEEE N42.13, 2004 | 2004 | Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides | 原採認標準 |
| 902 | Radiology | TFDA-01427 | ISO | ISO | 2021 | Lasers and laser-related equipment — Test methods | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 放射學科學 | | | 11146-1:2021 | | for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams | |
| 903 | Radiology 放射學科學 | TFDA-01428 | ISO | ISO 21254-1:2011 | 2011 | Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 1: Definitions and general principles | 原採認標準 |
| 904 | Radiology 放射學科學 | TFDA-01429 | ISO | ISO 21254-2:2011 | 2011 | Lasers and laser-related equipment -- Test methods for laser-induced damage threshold -- Part 2: Threshold determination | 原採認標準 |
| 905 | Radiology 放射學科學 | TFDA-01430 | ISO | ISO 2919:2012 | 2012 | Radiological protection -- Sealed radioactive sources -- General requirements and classification | 原採認標準 |
| 906 | Radiology 放射學科學 | TFDA-01431 | ISO | ISO/ASTM 51275:2013 | 2013 | Practice for use of a radiochromic film dosimetry system | 原採認標準 |
| 907 | Radiology 放射學科學 | TFDA-01432 | ISO | ISO/ASTM 51607:2013 | 2013 | Practice for use of an alanine-EPR dosimetry system | 原採認標準 |
| 908 | Radiology 放射學科學 | TFDA-01681 | ASTM | ASTM F2978 - 20 | 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 |
| 909 | Radiology 放射學科學 | TFDA-01701 | EN | EN 62220-1-1:2015 | 2015 | Medical electrical equipment - Characteristics of digital x-ray imaging devices - Part 1-1: Determination of the detective quantum efficiency - Detectors used in radiographic imaging | 原採認標準 |
| 910 | Radiology | TFDA-01702 | EN | EN 62570:2015 | 2015 | Standard practice for marking medical devices and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 放射學科學 | | | | | other items for safety in the magnetic resonance environment | |
| 911 | Radiology 放射學科學 | TFDA-01703 | IEC | IEC 60601-2-1:2020 | 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 |
| 912 | Radiology 放射學科學 | TFDA-01704 | IEC | IEC 60601-2-17:2013 | 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 |
| 913 | Radiology 放射學科學 | TFDA-01706 | IEC | IEC 60601-2-33:2010/ COR2:2016 | 2016 | 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 |
| 914 | Radiology 放射學科學 | TFDA-01707 | IEC | IEC 60601-2-36:2014 | 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 |
| 915 | Radiology 放射學科學 | TFDA-01708 | IEC | IEC 60601-2-37:2007/ AMD1:2015 | 2015 | Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment - Edition 2.1; Consolidated Reprint | 原採認標準 |
| 916 | Radiology | TFDA-01709 | IEC | IEC | 2016 | Medical electrical equipment Part 2-44: Particular | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 放射學科學 | | | 60601-2-44:2009 +AMD1:2012+A MD2:2016 | | 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 | |
| 917 | Radiology 放射學科學 | TFDA-01710 | IEC | IEC 60601-2-45:2011/ AMD1:2015 | 2015 | Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices - Edition 3.1; Consolidated Reprint | 原採認標準 |
| 918 | Radiology 放射學科學 | TFDA-01712 | IEC | IEC 60601-2-62:2013 | 2013 | Medical electrical equipment—Part 2–62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment | 原採認標準 |
| 919 | Radiology 放射學科學 | TFDA-01713 | IEC | IEC 60601-2-64:2014 | 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 |
| 920 | Radiology 放射學科學 | TFDA-01714 | IEC | IEC 60601-2-68:2014 | 2014 | Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-raybased image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment | 原採認標準 |
| 921 | Radiology | TFDA-01715 | IEC | IEC | 2015 | Medical electrical equipment – Part 2-8: Particular | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 放射學科學 | | | 60601-2-8:2010/ AMD 1:2015 | | requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV - Edition 2.1; Consolidated Reprint | |
| 922 | Radiology 放射學科學 | TFDA-01716 | IEC | IEC 60731:2011+A1:2 016 | 2016 | Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy - Edition 3.1; Consolidated Reprint | 原採認標準 |
| 923 | Radiology 放射學科學 | TFDA-01718 | ISO | ISO 11810:2015 | 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 |
| 924 | Radiology 放射學科學 | TFDA-01720 | ISO | ISO/ASTM 51707:2015 | 2015 | Guide for estimating uncertainties in dosimetry for radiation processing | 原採認標準 |
| 925 | Radiology 放射學科學 | TFDA-01859 | IEC | IEC 60601-2-28:2017 | 2017 | Medical electrical equipment - Part 2-28:Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis | 原採認標準 |
| 926 | Radiology 放射學科學 | TFDA-01861 | IEC | IEC 60601-2-63:2017 | 2017 | Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment | 原採認標準 |
| 927 | Radiology 放射學科學 | TFDA-01862 | IEC | IEC 60601-2-65:2017 | 2017 | Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 928 | Radiology 放射學科學 | TFDA-01863 | ISO | ISO 11554:2017 | 2017 | Optics and photonics -- Lasers and laser-related equipment -- Test methods for laser beam power, energy and temporal characteristics | 原採認標準 |
| 929 | Radiology 放射學科學 | TFDA-01864 | ISO | ISO 12052:2017 | 2017 | Health informatics -- Digital imaging and communication in medicine (DICOM) including workflow and data management | 原採認標準 |
| 930 | Radiology 放射學科學 | TFDA-01919 | IEC | IEC 60601-2-54:2009 +AMD1:2015+A MD2:2018 CSV | 2018 | Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy | 原採認標準 |
| 931 | Radiology 放射學科學 | TFDA-01920 | ISO | ISO 11670:2003/COR 1:2004 | 2004 | Lasers and laser-related equipment - Test methods for laser beam parameters - Beam positional stability | 原採認標準 |
| 932 | Radiology 放射學科學 | TFDA-01921 | ASTM | ASTM D7866-14a | 2014 | Standard Specification for Radiation Attenuating Protective Gloves | 原採認標準 |
| 933 | Radiology 放射學科學 | TFDA-02070 | IEC | IEC 61223-3-5:2019 | 2019 | Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X-ray equipment | 原採認標準 |
| 934 | Radiology 放射學科學 | TFDA-02071 | IEC | IEC 80601-2-26:2019 | 2019 | Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalograph | 原採認標準 |
| 935 | Radiology 放射學科學 | TFDA-02072 | ISO | ISO 11990:2018 | 2018 | Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes Part 2: Tracheal | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 936 | Radiology 放射學科學 | TFDA-02073 | ISO | ISO 11551:2019 | 2019 | Optics and optical instruments - Lasers and laser-related equipment - Test method for absorptance of optical laser components | 原採認標準 |
| 937 | Radiology 放射學科學 | TFDA-02074 | NEMA | DICOM PS3.1 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 1: Introduction and Overview | 原採認標準 |
| 938 | Radiology 放射學科學 | TFDA-02075 | NEMA | DICOM PS3.10 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 10: Media Storage and File Format for Media Interchange | 原採認標準 |
| 939 | Radiology 放射學科學 | TFDA-02076 | NEMA | DICOM PS3.11 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 11: Media Storage Application Profiles | 原採認標準 |
| 940 | Radiology 放射學科學 | TFDA-02077 | NEMA | DICOM PS3.12 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 12: Media Formats and Physical Media for Media Interchange | 原採認標準 |
| 941 | Radiology 放射學科學 | TFDA-02078 | NEMA | DICOM PS3.14 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function | 原採認標準 |
| 942 | Radiology 放射學科學 | TFDA-02079 | NEMA | DICOM PS3.15 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 15: Security and System Management Profiles | 原採認標準 |
| 943 | Radiology 放射學科學 | TFDA-02080 | NEMA | DICOM PS3.16 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 16: Content Mapping Resource | 原採認標準 |
| 944 | Radiology | TFDA-02081 | NEMA | DICOM PS3.17 | 2021 | Digital Imaging and Communications in Medicine | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 放射學科學 | | | 2021c | | (DICOM) Part 17: Explanatory Information | |
| 945 | Radiology 放射學科學 | TFDA-02082 | NEMA | DICOM PS3.18 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 18: Web Access to DICOM Persistent Objects (WADO) | 原採認標準 |
| 946 | Radiology 放射學科學 | TFDA-02083 | NEMA | DICOM PS3.19 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 19: Application Hosting | 原採認標準 |
| 947 | Radiology 放射學科學 | TFDA-02084 | NEMA | DICOM PS3.2 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 2: Conformance | 原採認標準 |
| 948 | Radiology 放射學科學 | TFDA-02085 | NEMA | DICOM PS3.20 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 20: Transformation of DICOM to and from HL7 Standards | 原採認標準 |
| 949 | Radiology 放射學科學 | TFDA-02086 | NEMA | DICOM PS3.3 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 3: Information Object Definitions | 原採認標準 |
| 950 | Radiology 放射學科學 | TFDA-02087 | NEMA | DICOM PS3.4 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 4: Service Class Specifications | 原採認標準 |
| 951 | Radiology 放射學科學 | TFDA-02088 | NEMA | DICOM PS3.5 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 5: Data Structures and Encoding | 原採認標準 |
| 952 | Radiology 放射學科學 | TFDA-02089 | NEMA | DICOM PS3.6 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 6: Data Dictionary | 原採認標準 |
| 953 | Radiology 放射學科學 | TFDA-02090 | NEMA | DICOM PS3.7 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 7: Message Exchange | 原採認標準 |
| 954 | Radiology 放射學科學 | TFDA-02091 | NEMA | DICOM PS3.8 2021c | 2021 | Digital Imaging and Communications in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 955 | Radiology 放射學科學 | TFDA-02092 | IEC | IEC 60601-2-43:2010 +AMD1:2017+A MD2:2019 CSV | 2019 | Medical electrical equipment - Part 2-43:Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures | 原採認標準 |
| 956 | Radiology 放射學科學 | TFDA-02193 | IEC | IEC 62471:2006 | 2006 | Photobiological safety of lamps and lamp systems | 110 年度新增採認標準 |
| 957 | Radiology 放射學科學 | TFDA-02194 | NEMA | XR 25 -2019 | 2019 | Computed Tomography Dose Check | 110 年度新增採認標準 |
| 958 | Radiology 放射學科學 | TFDA-02195 | NEMA | NEMA MS 14-2019 | 2019 | Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems | 110 年度新增採認標準 |
| 959 | Radiology 放射學科學 | TFDA-02196 | IEC | IEC TR 63183:2019 | 2019 | Guidance on error and warning messages for software used in radiotherapy | 110 年度新增採認標準 |
| 960 | Radiology 放射學科學 | TFDA-02197 | AAMI | AAMI RT3:2020 | 2020 | Radiation therapy machine characterization | 110 年度新增採認標準 |
| 961 | Radiology 放射學科學 | TFDA-02198 | IEC | IEC 60336 Edition 5.0 2020-12 | 2020 | Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics | 110 年度新增採認標準 |
| 962 | Sterility 滅菌 | TFDA-00034 | ISO | ISO 14644-4:2001 | 2001 | Cleanrooms and Associated Controlled Environments - Part 4: Design, Construction and Start-up | 原採認標準 |
| 963 | Sterility 滅菌 | TFDA-00035 | ISO | ISO 14698-1:2003 | 2003 | Cleanrooms and Associated Controlled Environments - Biocontamination Control - Part 1: General Principles and Methods | 原採認標準 |
| 964 | Sterility 滅菌 | TFDA-00036 | ISO | ISO | 2003 | Cleanrooms and Associated Controlled | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 菌 | | | 14698-2:2003/CO R 1:2004 | | Environments - Biocontamination Control - Part 2: Evaluation and Interpretation of Biocontamination Data | |
| 965 | Sterility 滅 菌 | TFDA-00351 | ISO | ISO 13408-4:2005 | 2005 | Aseptic processing of health care products —Part 4: Clean-in-place technologies | 原採認標準 |
| 966 | Sterility 滅 菌 | TFDA-00354 | ISO | ISO 14644-5:2004 | 2004 | Cleanrooms and associated controlled environments —Part 5: Operations | 原採認標準 |
| 967 | Sterility 滅 菌 | TFDA-00355 | ISO | ISO 14644-7:2004 | 2004 | Cleanrooms and associated controlled environments —Part 7: Separative devices (clean air hoods, gloveboxes, isolators and minienvironments) | 原採認標準 |
| 968 | Sterility 滅 菌 | TFDA-00524 | ISO | ISO 11140-3:2007 | 2007 | Sterilization of health care products -- Chemical indicators -- Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test | 原採認標準 |
| 969 | Sterility 滅 菌 | TFDA-00525 | ISO | ISO 11140-4:2007 | 2007 | Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration | 原採認標準 |
| 970 | Sterility 滅 菌 | TFDA-00526 | ISO | ISO 11140-5:2007 | 2007 | Sterilization of health care products -- Chemical indicators -- Part 5: Class 2 indicators for Bowie and Dick-type air removal tests | 原採認標準 |
| 971 | Sterility 滅 菌 | TFDA-00529 | ISO | ISO 13408-3:2006 | 2006 | Aseptic processing of health care products -- Part 3: Lyophilization | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 972 | Sterility 滅菌 | TFDA-00530 | ISO | ISO 13408-5:2006 | 2006 | Aseptic processing of health care products -- Part 5: Sterilization in place | 原採認標準 |
| 973 | Sterility 滅菌 | TFDA-00676 | CEN | EN 556-1:2001/AC:2006 | 2006 | Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices | 原採認標準 |
| 974 | Sterility 滅菌 | TFDA-00677 | ISO | ISO 17665-1:2006 | 2006 | Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices | 原採認標準 |
| 975 | Sterility 滅菌 | TFDA-00865 | ISO | ISO 14937:2009 | 2009 | Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices | 原採認標準 |
| 976 | Sterility 滅菌 | TFDA-00870 | ISO | ISO 15882:2008 | 2008 | Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results | 原採認標準 |
| 977 | Sterility 滅菌 | TFDA-00947 | ISO | ISO/TS 17665-2:2009 | 2009 | Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1 | 原採認標準 |
| 978 | Sterility 滅菌 | TFDA-01030 | AOAC | 6.2.02:2006 | 2006 | Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method | 原採認標準 |
| 979 | Sterility 滅菌 | TFDA-01031 | AOAC | 6.2.03:2006 | 2006 | Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method | 原採認標準 |
| 980 | Sterility 滅菌 | TFDA-01032 | AOAC | 6.2.05:2006 | 2006 | Testing Disinfectants Against Pseudomonas | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 菌 | | | | | aeruginosa,Hard Surface Carrier Test Method. | |
| 981 | Sterility 滅菌 | TFDA-01033 | AOAC | 6.3.02:2006 | 2006 | Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes. | 原採認標準 |
| 982 | Sterility 滅菌 | TFDA-01034 | AOAC | 6.3.05:2012 | 2012 | Sporicidal Activity of Disinfectants Method I. | 原採認標準 |
| 983 | Sterility 滅菌 | TFDA-01035 | AOAC | 6.3.06:2012 | 2012 | Tuberculocidal Activity of Disinfectants. | 原採認標準 |
| 984 | Sterility 滅菌 | TFDA-01036 | CNS | CNS 15449-2 | 2011 | 量測、控制及實驗室使用電氣設備安全規定－第2部：處理醫用材料及實驗室程序使用蒸汽之高壓滅菌鍋特殊規定 (Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes) | 原採認標準 |
| 985 | Sterility 滅菌 | TFDA-01037 | CNS | CNS 15690 | 2013 | 健康照護產品滅菌－用語 (Sterilization of health care products – Vocabulary) | 原採認標準 |
| 986 | Sterility 滅菌 | TFDA-01038 | CNS | CNS 15691-1 | 2013 | 健康照護產品之無菌操作－第1部：一般要求 Aseptic processing of health care products – Part 1: General requirements (IDE ISO 13408-1:2006) | 原採認標準 |
| 987 | Sterility 滅菌 | TFDA-01039 | CNS | CNS 15691-2 | 2013 | 健康照護產品之無菌操作－第2部：過濾 Aseptic processing of health care products – Part 2: Filtration (IDE ISO 13408-2:2006) | 原採認標準 |
| 988 | Sterility 滅菌 | TFDA-01040 | CNS | CNS 15691-3 | 2013 | 健康照護產品之無菌操作－第3部：冷凍乾燥無菌操作 Aseptic processing of health care products – | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | Part 3: Lyophilization (IDE ISO 13408-3:2006) | |
| 989 | Sterility 滅菌 | TFDA-01041 | CNS | CNS 15691-4 | 2013 | 健康照護產品之無菌操作－第 4 部：原地清潔 Aseptic processing of health care products – Part 4: Clean-in-place technologies (IDE ISO 13408-4:2005) | 原採認標準 |
| 990 | Sterility 滅菌 | TFDA-01042 | CNS | CNS 15691-5 | 2013 | 健康照護產品之無菌操作－第 5 部：原地滅菌 Aseptic processing of health care products – Part 5: Sterilization in place (IDE ISO 13408-5:2006) | 原採認標準 |
| 991 | Sterility 滅菌 | TFDA-01043 | CNS | CNS 15691-6 | 2013 | 健康照護產品之無菌操作－第 6 部：隔離裝置系統 Aseptic processing of health care products – Part 6: Isolator systems (IDE ISO 13408-6:2005) | 原採認標準 |
| 992 | Sterility 滅菌 | TFDA-01047 | ISO | ISO 13408-6:2021 | 2021 | Aseptic processing of health care products — Part 6: Isolator systems | 原採認標準 |
| 993 | Sterility 滅菌 | TFDA-01048 | ISO | ISO 14160:2020 | 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 |
| 994 | Sterility 滅菌 | TFDA-01049 | ISO | ISO 14644-8:2013 | 2013 | Cleanrooms and associated controlled environments -- Part 8: Classification of air cleanliness by chemical concentration (ACC) | 原採認標準 |
| 995 | Sterility 滅菌 | TFDA-01051 | ISO | ISO/ASTM 52701:2013 | 2013 | Guide for performance characterization of dosimeters and dosimetry systems for use in | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | | | | | | radiation processing | |
| 996 | Sterility 滅菌 | TFDA-01721 | AAMI | AAMI TIR35:2016 | 2016 | Sterilization of health care products—Radiation sterilization—Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits | 原採認標準 |
| 997 | Sterility 滅菌 | TFDA-01722 | CNS | CNS 14622-1 | 2014 | 健康照護產品滅菌－生物指示劑－第 1 部：一般 (Sterilization of health care products – Biological indicators – Part 1: General requirements) | 原採認標準 |
| 998 | Sterility 滅菌 | TFDA-01723 | CNS | CNS 14622-2 | 2014 | 健康照護產品滅菌－生物指示劑－第 2 部：環氧乙烷滅菌程序之生物指示劑 (Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes) | 原採認標準 |
| 999 | Sterility 滅菌 | TFDA-01724 | CNS | CNS 14622-3 | 2014 | 健康照護產品滅菌－生物指示劑－第 3 部：濕熱滅菌程序之生物指示劑 (Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes) | 原採認標準 |
| 1000 | Sterility 滅菌 | TFDA-01725 | CNS | CNS 14622-4 | 2014 | 健康照護產品滅菌－生物指示劑－第 4 部：乾熱滅菌程序之生物指示劑 (Sterilization of health care products – Biological indicators – Part 4: Biological indicators for dry heat sterilization processes) | 原採認標準 |
| 1001 | Sterility 滅菌 | TFDA-01726 | CNS | CNS 14622-5 | 2014 | 健康照護產品滅菌－生物指示劑－第 5 部：低溫 | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 菌 | | | | | 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) | |
| 1002 | Sterility 滅菌 | TFDA-01727 | CNS | CNS 15758-1 | 2014 | 最終滅菌醫療器材之包裝－第 1 部：材料、無菌屏障系統及包裝系統之要求(Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems) | 原採認標準 |
| 1003 | Sterility 滅菌 | TFDA-01728 | EN | EN 14180:2014 | 2014 | Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing | 原採認標準 |
| 1004 | Sterility 滅菌 | TFDA-01729 | EN | EN 1422:2014 | 2014 | Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods | 原採認標準 |
| 1005 | Sterility 滅菌 | TFDA-01730 | EN | EN 16615:2015 | 2015 | Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2) | 原採認標準 |
| 1006 | Sterility 滅菌 | TFDA-01731 | EN | EN 556-2:2015 | 2015 | Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” Part 2: Requirements for aseptically processed medical devices | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 1007 | Sterility 滅菌 | TFDA-01733 | ISO | ISO 11138-1:2017 | 2017 | Sterilization of health care products — Biological indicators Part 1: General requirements | 原採認標準 |
| 1008 | Sterility 滅菌 | TFDA-01734 | ISO | ISO 11138-2:2017 | 2017 | Sterilization of health care products — Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes | 原採認標準 |
| 1009 | Sterility 滅菌 | TFDA-01735 | ISO | ISO 11138-3:2017 | 2017 | Sterilization of health care products - Biological indicators Part 3: Biological indicators for moist heat sterilization processes | 原採認標準 |
| 1010 | Sterility 滅菌 | TFDA-01736 | ISO | ISO 11138-4:2017 | 2017 | Sterilization of health care products - Biological indicators Part 4: Biological indicators for dry heat sterilization processes | 原採認標準 |
| 1011 | Sterility 滅菌 | TFDA-01737 | ISO | ISO 11138-5:2017 | 2017 | Sterilization of health care products — Biological indicators Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes | 原採認標準 |
| 1012 | Sterility 滅菌 | TFDA-01738 | ISO | ISO 11140-1:2014 | 2014 | Sterilization of health care products -- Chemical indicators -- Part 1: General requirements | 原採認標準 |
| 1013 | Sterility 滅菌 | TFDA-01741 | ISO | ISO 13408-7:2012 | 2012 | Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products - CORR: August 31, 2015 | 原採認標準 |
| 1014 | Sterility 滅菌 | TFDA-01742 | ISO | ISO 14644-1:2015 | 2015 | Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration - Second Edition | 原採認標準 |
| 1015 | Sterility 滅菌 | TFDA-01743 | ISO | ISO | 2015 | Cleanrooms and Associated Controlled | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 菌 | | | 14644-2:2015 | | Environments - Part 2: Specification for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1 | |
| 1016 | Sterility 滅菌 | TFDA-01744 | ISO | ISO 20857:2010 | 2010 | Sterilization of health care products _ Dry heat _ Requirements for the development, validation and routine control of a sterilization process for medical devices | 原採認標準 |
| 1017 | Sterility 滅菌 | TFDA-01745 | ISO | ISO/TS 16775:2014 | 2014 | Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 | 原採認標準 |
| 1018 | Sterility 滅菌 | TFDA-01761 | ISO | ISO 11137-2:2013 | 2013 | Sterilization of health care products - Radiation Part 2: Establishing the sterilization dose | 原採認標準 |
| 1019 | Sterility 滅菌 | TFDA-01762 | ISO | ISO 13408-1:2008/A MD 1:2013 | 2013 | Aseptic processing of health care products Part 1: General requirements | 原採認標準 |
| 1020 | Sterility 滅菌 | TFDA-01865 | AAMI | AAMI ST55:2016 | 2016 | Table-Top Steam Sterilizers | 原採認標準 |
| 1021 | Sterility 滅菌 | TFDA-01866 | ISO | ISO 11737-1:2018 | 2018 | Sterilization of medical devices -- Microbiological methods -- Part 1:Determination of a population of microorganisms on products | 原採認標準 |
| 1022 | Sterility 滅菌 | TFDA-01867 | ISO | ISO 13408-2:2018 | 2018 | Aseptic Processing of Health Care Products - Part 2: Filtration | 原採認標準 |
| 1023 | Sterility 滅菌 | TFDA-01922 | AAMI | AAMI ST50:2004/(R)20 | 2018 | Dry heat (heated air) sterilizers | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 1024 | Sterility 滅菌 | TFDA-01923 | AAMI | AAMI ST8 : 2013(R2018) | 2018 | Hospital steam sterilizers | 原採認標準 |
| 1025 | Sterility 滅菌 | TFDA-01924 | AAMI | AAMI ST24:1999/(R)2018 | 2018 | Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities | 原採認標準 |
| 1026 | Sterility 滅菌 | TFDA-01925 | AAMI | AAMI ST77:2013/(R)2018 | 2018 | Containment devices for reusable medical device sterilization, 2nd ed. | 原採認標準 |
| 1027 | Sterility 滅菌 | TFDA-02093 | ISO | ISO 18472:2018 | 2018 | Sterilization of health care products —Biological and chemical indicators —Test equipment | 原採認標準 |
| 1028 | Sterility 滅菌 | TFDA-02094 | ISO | ISO 11138-7:2019 | 2019 | Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results | 原採認標準 |
| 1029 | Sterility 滅菌 | TFDA-02095 | ASTM | ASTM F2315-18 | 2018 | Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels | 原採認標準 |
| 1030 | Sterility 滅菌 | TFDA-02096 | ASTM | ASTM F2450-18 | 2018 | Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products | 原採認標準 |
| 1031 | Sterility 滅菌 | TFDA-02097 | ISO | ISO 11135:2014/AMD 1:2018 ° ISO 11135:2014+A1:2 | 2018 | Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 1032 | Sterility 滅菌 | TFDA-02098 | ISO | ISO 11607-1:2019 | 2019 | Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems | 原採認標準 |
| 1033 | Sterility 滅菌 | TFDA-02099 | ISO | ISO 11607-2:2019 | 2019 | Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes | 原採認標準 |
| 1034 | Sterility 滅菌 | TFDA-02100 | ISO | ISO 11137-1:2015+A2:2018 | 2018 | Sterilization of health care products - Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices | 原採認標準 |
| 1035 | Sterility 滅菌 | TFDA-02101 | ISO | ISO 14644-3:2019 | 2019 | Cleanrooms and associated controlled environments —Part 3: Test methods | 原採認標準 |
| 1036 | Sterility 滅菌 | TFDA-02102 | ISO | ISO 11737-2:2019 | 2019 | Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process | 原採認標準 |
| 1037 | Sterility 滅菌 | TFDA-02103 | ISO | ISO/ASTM 52628:2020 | 2020 | Practice for dosimetry in radiation processing | 原採認標準 |
| 1038 | Sterility 滅菌 | TFDA-02199 | ASTM | F1980 - 16 | 2016 | Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices | 110 年度新增採認標準 |
| 1039 | Sterility 滅菌 | TFDA-02200 | ANSI AAMI | ST72:2019 | 2019 | Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing | 110 年度新增採認標準 |
| 1040 | Sterility 滅菌 | TFDA-02201 | ASTM | ISO/ASTM | 2019 | Practice for use of a polymethylmethacrylate | 110 年度新增 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 菌 | | ISO | 51276:2019 | | dosimetry system | 採認標準 |
| 1041 | Sterility 滅菌 | TFDA-02202 | EN ISO | EN ISO 25424:2019 | 2019 | Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices | 110 年度新增採認標準 |
| 1042 | Sterility 滅菌 | TFDA-02203 | ASTM | F2475-20 | 2020 | Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials | 110 年度新增採認標準 |
| 1043 | Sterility 滅菌 | TFDA-02204 | ASTM | ASTM F2097-20 | 2020 | Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products | 110 年度新增採認標準 |
| 1044 | Sterility 滅菌 | TFDA-02205 | ASTM ISO | ASTM ISO 51818 Fourth edition 2020-06 | 2020 | Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV | 110 年度新增採認標準 |
| 1045 | Sterility 滅菌 | TFDA-02206 | ASTM | ASTM F3004-13 (Reapproved 2020) | 2020 | Standard Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound | 110 年度新增採認標準 |
| 1046 | Sterility 滅菌 | TFDA-02207 | ASTM | ASTM F17-20 | 2020 | Standard Terminology Relating to Flexible Barrier Packaging | 110 年度新增採認標準 |
| 1047 | Sterility 滅菌 | TFDA-02208 | ANSI AAMI | ANSI AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 | 2020 | (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities | 110 年度新增採認標準 |
| 1048 | Tissue | TFDA-01105 | ASTM | ASTM F2603 - | 2020 | Standard Guide for Interpreting Images of | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | Engineering 組織工程 | | | 06(2020) | | Polymeric Tissue Scaffolds | |
| 1049 | Tissue Engineering 組織工程 | TFDA-01748 | ISO | ISO 22442-2:2020 | 2020 | Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling | 原採認標準 |
| 1050 | Tissue Engineering 組織工程 | TFDA-01749 | ISO | ISO 22442-3:2007 | 2007 | Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents | 原採認標準 |
| 1051 | Tissue Engineering 組織工程 | TFDA-01868 | ASTM | ASTM F2064-17 | 2017 | Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Products Application | 原採認標準 |
| 1052 | Tissue Engineering 組織工程 | TFDA-01869 | ASTM | ASTM F3206-17 | 2017 | Standard Guide for Assessing Medical Device Cytocompatibility with Delivered Cellular Therapies | 原採認標準 |
| 1053 | Tissue Engineering 組織工程 | TFDA-01870 | ASTM | ASTM F3207-17 | 2017 | Standard Guide for in vivo Evaluation of Rabbit Lumbar Intertransverse Process Spinal Fusion Model | 原採認標準 |
| 1054 | Tissue Engineering 組織工程 | TFDA-02104 | ASTM | ASTM F3224-17 | 2017 | Standard Test Method for Evaluating Growth of Engineered Cartilage Tissue using Magnetic Resonance Imaging. | 原採認標準 |
| 1055 | Tissue Engineering | TFDA-02105 | ASTM | ASTM F2212 - 20 | 2020 | Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 組織工程 | | | | | and Substrates for Tissue Engineered Medical Products (TEMPs) | |
| 1056 | Tissue Engineering 組織工程 | TFDA-02209 | ASTM | F2150-19 | 2019 | Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Regenerative Medicine and Tissue-Engineered Medical Products | 110 年度新增採認標準 |
| 1057 | Tissue Engineering 組織工程 | TFDA-02210 | ASTM | F2739-19 | 2019 | Standard Guide for Quantifying Cell Viability and Related Attributes within Biomaterial Scaffolds | 110 年度新增採認標準 |
| 1058 | Tissue Engineering 組織工程 | TFDA-02211 | ISO | ISO 22442-1 Third edition 2020-09 | 2020 | Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management | 110 年度新增採認標準 |
| 1059 | Neurology 神經學 | TFDA-00709 | ISO | ISO 7197:2006 ; ISO 7197:2006/Cor 1:2007 | 2007 | Technical Corrigendum1- Neurosurgical implants -- Sterile, single-use hydrocephalus shunts and components | 原採認標準 |
| 1060 | Neurology 神經學 | TFDA-01324 | IEC | IEC 60601-2-23:2011 | 2011 | Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment - Edition 3.0 | 原採認標準 |
| 1061 | Neurology 神經學 | TFDA-01752 | IEC | IEC 60601-2-10:2016 | 2016 | Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators | 原採認標準 |
| 1062 | Neurology 神經學 | TFDA-01926 | ASTM | ASTM F647 - 94(2014) | 2014 | Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 1063 | Neurology 神經學 | TFDA-01928 | AAMI | AAMI NS4:2013/(R)2017 | 2017 | Transcutaneous electrical nerve stimulators | 原採認標準 |
| 1064 | Nanotechnology 奈米科技 | TFDA-01871 | ISO | ISO 29701:2010 | 2010 | Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems—Limulus amoebocyte lysate (LAL) test. | 原採認標準 |
| 1065 | Nanotechnology 奈米科技 | TFDA-01872 | ISO | ISO/TR 13014:2012/COR 1:2012 | 2012 | Nanotechnologies—Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment | 原採認標準 |
| 1066 | Nanotechnology 奈米科技 | TFDA-02212 | ISO | ISO 21363 First edition 2020-06 | 2020 | Nanotechnologies - Measurements of particle size and shape distributions by transmission electron microscopy | 110 年度新增 採認標準 |
| 1067 | Nanotechnology 奈米科技 | TFDA-02213 | ASTM | ASTM E3247-20 | 2020 | Standard Test Method for Measuring the Size of Nanoparticles in Aqueous Media Using Dynamic Light Scattering | 110 年度新增 採認標準 |
| 1068 | General II (ES/EMC) 通用(醫療電 子/電磁相 容) | TFDA-01003 | CNS | CNS 14912 | 2013 | 醫電設備之安全標準規範 (Fundamental aspects of safety standards for medical electrical equipment) | 原採認標準 |
| 1069 | General II (ES/EMC) 通用(醫療電 | TFDA-01004 | CNS | CNS 14913 | 2013 | 醫電設備之圖形符號 (Graphical symbols for electrical equipment in medical practice) | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| 1070 | General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01005 | IEC | IEC 60601-1:2005/A MD1:2012/ISH1: 2021 | 2021 | Interpretation Sheet 1 - Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | 原採認標準 |
| 1071 | General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01007 | IEC | IEC 60601-1-2:2014/ AMD1:2020 CSV | 2020 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests | 原採認標準 |
| 1072 | General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01008 | IEC | IEC 60601-1-6:2010/ AMD2:2020 | 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 |
| 1073 | General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01009 | IEC | IEC 60601-1-8:2006+ AMD1:2012+AM D2:2020 CSV | 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 |
| 1074 | General II | TFDA-01011 | IEC | IEC | 2020 | Electrical equipment for measurement, control and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | (ES/EMC) 通用(醫療電 子/電磁相 容) | | | 61326-1:2020 | | laboratory use - EMC requirements - Part 1: General requirements | |
| 1075 | General II (ES/EMC) 通用(醫療電 子/電磁相 容) | TFDA-01753 | IEC | IEC 60601-1-10:2007/ AMD2:2020 | 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 |
| 1076 | General II (ES/EMC) 通用(醫療電 子/電磁相 容) | TFDA-01754 | IEC | IEC 60601-1-11:2015/ AMD1:2020 | 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 medical electrical systems used in the home healthcare environment | 原採認標準 |
| 1077 | General II (ES/EMC) 通用(醫療電 子/電磁相 容) | TFDA-01755 | IEC | IEC 60601-1-12:2014/ AMD1:2020 | 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 |
| 1078 | General II (ES/EMC) 通用(醫療電 | TFDA-01757 | IEC | IEC TR 60601-4-2:2016 | 2016 | Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and | 原採認標準 |

110 年度衛生福利部食品藥物管理署採認醫療器材標準

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| | 子/電磁相容) | | | | | medical electrical systems | |
| 1079 | General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01758 | IEC | IEC/TR 62354:2014 | 2014 | General testing procedures for medical electrical equipment | 原採認標準 |
| 1080 | General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01759 | IEEE | IEEE/ANSI C63.27-2017 | 2017 | American National Standard for Evaluation of Wireless Coexistence | 原採認標準 |
| 1081 | General II (ES/EMC) 通用(醫療電子/電磁相容) | TFDA-01929 | IEC | IEC/TR 60601-4-1:2017 | 2017 | Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy | 原採認標準 |