附表、醫療器材品項及其對應臨床前測試基準或標準

110年5月1日更新

A.品項名稱 Device name	B.分級分類代碼 Classification number	C.對應臨床前測試基準 Guidance for pre-clinical testing	D.對應標準	
			1.功能性(垂直)標準 Essential performance (vertical) standards	2.共通安全性(水平)標準 General Safety (horizontal) standards
紅外線耳溫槍 (Infrared ear thermometer)	J.2910	紅外線耳溫槍臨床前測試基準	1. ISO 80601-2-56:2017/Amd 1: 2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或 2. ASTM E1965 - 98(2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature；或 3.中華民國國家標準 CNS 15042 間歇性測定患者體溫之紅外線體溫計 (2007)	1. EC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and ssential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests；及 3. 產品與人體接觸部位(如探頭、護套等)：ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
紅外線額溫槍(Infrared Forehead thermometer)	J.2910	無	1. ISO 80601-2-56:2017/Amd 1: 2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或 2. ASTM E1965 - 98(2009) Standard Specification for Infrared	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic

			Thermometers for Intermittent Determination of Patient Temperature；或 3.中華民國國家標準 CNS 15042 間歇性測定患者體溫之紅外線體溫計 (2007)	disturbances – Requirements and tests；及 3. 產品與人體接觸部位(如探頭、護套等)：ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
電子體溫計 (Clinical electronic thermometer)	J.2910	臨床電子體溫計臨床前測試基準	1. ASTM E 1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature (2018)；或 2. ISO 80601-2-56:2017/Amd 1: 2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或 3.中華民國國家標準 CNS 15043 間歇性測定患者體溫之電子式體溫計 (2007)	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests；及 3. 產品與人體接觸部位(如探頭、護套等)：ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
外科用覆蓋巾 (Surgical drape)	I.4370	外科用覆蓋巾臨床前測試基準	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	1. ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process；及 2. 進行滅菌確效 (Sterilization validation) (見備註)確保 SAL (Sterility assurance level)小於10^{-6}；及 3. 若為重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008/R2018), section 6-Laundry processing

				recommendations and section 7-Inspection, testing, and maintenance of laundered textiles
外科手術衣 (surgical gowns)	I.4040	無	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	1. ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process；及 2. 進行滅菌確效 (Sterilization validation) (見備註)確保 SAL (Sterility assurance level)小於10^{-6}；及 3. 若為重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008/R2018), section 6-Laundry processing recommendations and section 7-Inspection, testing, and maintenance of laundered textiles
外科手術燈 (Surgical lamp)	I.4580	外科手術燈臨床前測試基準	IEC 60601-2-41:2009+Amd 1: 2013Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances –Requirements and tests
靜電器(電位治療器) (Static Electric	O.0001	靜電器(電位治療器)臨床前測試基準	JIS T 2003:2018 Electric therapy apparatus for home use	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及

Therapy Apparatus)				2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
紅外線燈(治療器) (Infrared Lamp (therapy apparatus))	O.5500	紅外線燈(治療器) 臨床前測試基準	JIS T 0601-2-203:2015 Medical electrical equipment - Part 2-203: Particular requirements for the basic safety and essential performance of infrared therapy equipment	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

備註：滅菌確效需視滅菌方法，以對應之國際公定標準進行—

1. EO 滅菌- ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
2. 輻射滅菌- ISO 11137-1:2015 Sterilization of health care products- Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices 及 ISO 11137-2:2015 Sterilization of health care products- Radiation - Part 2: Establishing the sterilization dose 及 ISO 11137-3:2017 Sterilization of health care products- Radiation - Part 3Guidance on dosimetric aspects
3. 濕熱滅菌- ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices