附表、醫療器材品項及其應符合之臨床前測試基準或標準

105 年 07 月 01 日更新

Conformity assessment of medical device to the recognized standards and guidance

A. 品項名稱 Device name	B. 分級分類代碼 Classification Number	C. 臨床前測試基準 Guidance for pre-clinical testing	D. 採認標準 Recognized standards	
			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 80601-2-56:2012 Medical electrical equipment. 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. IEC 60601-1 :2005+AMD1:2012 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.
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 1112-00(2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature；或	1. IEC 60601-1 :2005+AMD1:2012 Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical

			2. ISO 80601-2-56:2012 Medical electrical equipment. 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)	equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
外科用覆蓋巾 (Surgical drape)	I.4370	外科用覆蓋巾臨床前測試基準	1. EN 13795:2011 +A1:2013 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels.	1. ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)；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. ※重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008), 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	1. EN 13795:2011+A1:2013 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance	1. ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)；及 2. 進行滅菌確效 (Sterilization validation) (見備註)確保SAL (Sterility assurance level)小於 10^{-6}；及

			requirements and performance levels.	3. ※重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008), section 6-Laundry processing recommendations and section 7-Inspection, testing, and maintenance of laundered textiles.

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. 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. Establishing the sterilization dose 及 ISO 11137-3:2006 Sterilization of health care products. Radiation. Guidance 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