

Draft Medical device product items that shall Accord specification, testing method and performance

Classification Number	Classification Name	Class	Product Category	Specification, Testing Method and Performance	Implementation Date
O.3825	Mechanical Walker	1	Walking Frames without Accessories	According to Product Characteristics, Non-clinical performance data of the Fatigue test, Static loading test, Static leg-strength test, Forward stability test and Backward stability test should comply with CNS 15037-1, ISO 11199-1 or the others equivalent international standards.	One year after announcement
			Rollators	According to Product Characteristics, Non-clinical performance data of the Forward-direction stability test, Backward-direction stability test, Sideway-direction stability test, Brake tests, Handgrip test, Rubber tip test, Resting seat test, Static loading test, Fatigue test and Final inspection should comply with CNS 15037-2, ISO 11199-2 or the others equivalent international standards.	
			Walking Tables	According to Product Characteristics, Non-clinical performance data of the Forward stability test, Backward stability test, Sideways stability test, Brake test, Resting seat test, Static strength test, Fatigue test and Final inspection should comply with CNS 15037-3, ISO 11199-3 or the others equivalent international standards.	
G.3300	Hearing Aid	1	Air-conduction Hearing Aid	According to Product Characteristics, Non-clinical performance data should comply with IEC 60601-1(Electrical safety test), IEC 60601-1-2(Electromagnetic compatibility test), ISO 10993-1(Cytotoxicity), ISO 10993-5(Sensitization), ISO 10993-10(Irritation or Intracutaneous reactivity) and ANSI S3.22(Electroacoustic performance) or the others equivalent international standards.	One year after announcement
I.4040	Medical Apparel	1	Disposable Isolation Gown	According to Product Characteristics, Non-clinical performance data of the Hydrostatic pressure and Impact penetration should comply with CNS 14798(T5019) P1 level or the others equivalent international standards.	One year after announcement