

Draft Product items of the medical device — Requirements for specifications, test methods and performance

Classification Number	Classification Name	Class	Product Category	Specification, Testing Method and Performance	Implementation Date
G.3300	Hearing Aid	1	Air-conduction Hearing Aid	According to product characteristics, pre-clinical performance reports should comply with IEC 60601-1(Electrical safety test), IEC 60601-1-2(Electromagnetic compatibility test) 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, pre-clinical performance reports 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
		1, 2	Medical Face Masks	The quality requirements report of the Free formaldehyde, Forbidden azo colorants, and Migratable fluorescent substances in colored or dyed medical face masks should comply with CNS 14774.	
O.3825	Mechanical Walker	1	Walking Frames without Accessories	According to product characteristics, pre-clinical performance reports of the Fatigue test, Static loading test, Static leg-strength test, Forward stability test, Backward stability test and Sideways 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, pre-clinical performance reports 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, pre-clinical performance reports 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.	

Note: if the product performance/specifications have been described in the identification provisions of medical device product items shall also be submitted.