



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Hangzhou Dunli Medical Instruments Co.,Ltd

Address: No.1 Dunli Road,Renhe Street,Yuhang,
Hangzhou,China •

SRN: /

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam,
Netherlands

Product Category See Annex

Classification: Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

**Conformity Assessment
Procedure:** Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008+A1:2013

ISO 10993-1:2018

EN ISO 10993-5:2009

DIN EN ISO 3452-1:2014

ISO 17966:2016

ISO 9227:2017

EN 62366-1:2015







ISO 2409:2020

Signature: 
Name / Position: Renofan GM

Date: 04/28/2021

Place: Hangzhou / China

ANNEX

Product Name	Model	Basic UDI-DI	Picture
Commode chair	DL3010064	697439636DL3010064T7	
	DL3010068		
	DL30100EL		
	DL30100FR		
	DL36100KD		
	DL36100MB		
	DL30100XW		