

# Declaration of Conformity

of conformity of the factory production control  
No. DOC-MDR-20210712R21

of conformity based on full quality assurance issued according to point 11 of Annex  
III of the Directive 2017/745/EU

Product name: Shower stool

Model(s): 341967, 342314, 344418, 344419, 344420, 343591, 343908, 344421, 344422,  
344423, 344424, 344425, 344426, 344427, 344428, 344429, 344430, 343909, 344431, 343910,  
343911, 343592, 344432, 344433, 344434, 344435, 344436, 344437, 344438, 344439, 344440,  
344441, 344442, 344443, 344444, 344445, 344446, 344447, 344448, 344449, 344450, 343656,  
344451, 344452, 344453, 344454, 344455, 343925

Type: Class I

UDI DI Basic: (01)69416434196722(10)20210615A(11)210615(17)230614

Hangzhou Royal Craft Import and Export CO., LTD

Room 2403-2404, Silver Flying Building, 1505 BinShen Road, HangZhou, China

Standard(s) used for showing compliance with the essential  
requirements in the specified directive(s):  
EN ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:  
2010, EN ISO 17966:2016

The referred report(s) show that the product complies with standard(s) recognized as giving  
presumption of compliance with the essential requirements in the specified EU Directive(s). The  
applicant may affix the CE marking to the product.

The submitted sample of the above product has been tested for CE marking according to  
the related European Directives, Medical Devices Regulation (EU) 2017/745

## European Authorized Representative

Authorised representative in EEA

Name: M/s CMC Medical Devices & Drugs S.L.

ADD: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Tel: +34951214054

Fax: +34952330100



Signature of Authorized Person  
(AnnieWang)

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