

# Declaration of Conformity

of conformity of the factory production control  
No. DOC-MDR-20210712R2

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

Product name: Grab Rail

Model(s): 343593, 344515, 344516, 344517, 344511, 344518, 344512, 344519, 344520,  
344521, 344522, 344523, 344524, 343594, 344525, 344526, 344527, 344528, 344529, 343601,  
344513, 344514, 344530, 344531, 344532, 344533, 344534, 344535, 344536, 344537, 344538,  
344539, 344540, 344541, 344542, 344543, 344544, 344545, 344126, 344127, 344128, 344546,  
344547, 344548, 344619, 344620

Type: Class I

UDI DI Basic: (01)06941643435931(10)XXXXX(11)XXXXXX(17)XXXXXX

Hangzhou Royal Craft Import and Export CO., LTD

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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 17966-16.5:2016

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

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*Paul*

Signature of Authorized Person  
(AnnieWang)

DOC No: H-YQ-MD-21071208  
Issue date: Jul.12, 2021