

# EU Declaration of Conformity

Manufacturer: QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD  
NO.1 GUANGDONG ROAD,JIANGSHAN INDUSTRIAL  
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European Representative: CMC Medical Devices & Drugs S.L.  
Horacio Lengo Nº 18, CP 29006, Málaga, Spain  
SRN: ES-AR-000000293

Product Name: Disposable Medical Face Mack  
Model Number: C007 C010 C016 C020  
Specification: 14.5\*9cm 17.5\*9.5cm  
GMDN Code: 35177

Classification (MDR, Rule 1): Class I

Conformity Assessment Route: Annex II + Annex III of MDR

We hereby state that:

Those above products with CE marking which are manufactured by our company all comply with Regulation (EU) 2017/745 on Medical Devices, and realize their expected uses.

Applied standards, common specification, guidance:

EN 14683:2019+AC:2019  
EN 1041:2008  
EN 62366-1:2015+AC:2015  
ISO 10993-1:2018  
ISO 10993-5:2009  
ISO 10993-10:2010  
EN ISO 13485:2016  
EN ISO 15223-1:2016  
EN ISO 14971:2012  
ASTM D 4169-2016  
MDCG 2019-15

Signature: *Liu Baoyu*

Name: General Manager  
Position: Qingdao/ 18 June 2021  
Place/date: 青岛海诺生物工程有限公司

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