

## **EU Declaration of Conformity**

Manufacturer: QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD  
NO.1 GUANGDONG ROAD,JIANGSHAN INDUSTRIAL  
ZONE LAIXI CITY, QINGDAO, CHINA  
Tel: +86-532-86463333/86464444

SRN: /

European Representative: CMC Medical Devices & Drugs S.L.  
Horacio Lengo N° 18, CP 29006, Málaga, Spain

Product Name: Disposable Medical Face Mask  
Product Type: EN14683:2019 TYPE IIR  
Product Code: C010  
Specification: 17.5cmx9.5cm  
GMDN Code: 12-458

Classification (MDD, Annex IX): Class I, Rule 1.

Conformity Assessment Route: Annex IX of MDD 93/42/EEC.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Applied standards, common specification, guidance:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, MDCG 2019-15.

Signature: *Gong Daming*

Name: General Manager  
Position: General Manager  
Place/date: Qingdao/ 5 Apr 2020

File No.: HN/CE01-01, ver.A/0

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