

EU Declaration of Conformity

Manufacturer: QINGDAO HAINUO BIOLOGICAL ENGINEERING CO., LTD
NO.1 GUANGDONG ROAD,JIANGSHAN INDUSTRIAL
ZONE LAIXI CITY, QINGDAO, CHINA
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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 I
Product Code: C007
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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