

# EU Declaration of Conformity

Manufacturer: GUANGDONG RUIYANG PHARMACEUTICAL CO.,LTD.  
Economic Corridor Development Zone,Lianjiang  
City,Guangdong Province, China  
Tel:+86-759-6609990

SRN: /

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

SRN: /

Product Name: Disposable Medical Face Mask  
Specification: 17.5cm×9.5cm; 14.5×9.5cm  
GMDN Code: 35177  
UMDN Code: 12-458  
UDI-DI: /

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

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:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

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:

Name: 莫建康  
Position: General Manager  
Place/date: 2021.4.1  
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