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 Nº 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 + 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:
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: 黄进廖
Position: General Manager
Place/date:
File No.: GDRY/CE02-01-01, ver.A/0

CE

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/01042020.1

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

GUANGDONG RUIYANG PHARMACEUTICAL CO.,LTD.
Economic Corridor Development Zone,Lianjiang City,Guangdong Province,China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/406/2020**

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Issued on: 01/04/2020

Valid until: 31/03/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Disposable Medical Face Mask

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