

EU Declaration of Conformity

Manufacturer: Chongqing Paxijia Biotechnology Co., Ltd.
No. 27-5, Fengsheng Road, Jiulongpo District, Chongqing,
China

SRN: /

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

SRN: /

Product Name: Surgical Mask

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:

Position:

Place/date:



General Manager

China, May 1st, 2020

CE