

EU Declaration of Conformity

Manufacturer: Jiangxi Zhonghong Pulin Medical Products Co., Ltd
Yinshawan Park, High-tech Industrial Park, Hukou County, Jiujiang
City, Jiangxi Province, China

SRN: CN-MF-000002382

European
Representative: Continental Medical B.V.
John M. Keynesplein 1-27, 1066EP, Amsterdam, Noord, Netherlands

SRN: NL-AR-000022261

Product Name: Disposable Nitrile Exam Gloves/Nitrile Examination Gloves
(Sizes XS, S, M, L, XL)

GMDN Code: 56286
UMDN Code: 11882
Basic UDI: 697419638JXPLN01BR

Classification (MDR, Annex VIII): Class 1, 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. Jiangxi Zhonghong Pulin Medical Products Co.,Ltd. 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 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN ISO 14971:2019/A11:2021, EN 62366-1:2015/A1:2020, ISO 10993-1:2018, ISO 10993-5:2009, EN ISO 10993-10:2023, ASTM D4169-22, ISO 188:2023, ISO 21171:2006, ASTM D6319-19, ASTM D5151-19, ASTM D6124-06 (2022), ASTM D7160-16 (2023), MDCG 2019-15.

Signature:

Name:

Position:

Place/date



Jia Fujun

PRRC

Jiujiang City, 2024-5-23