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:	/
European Representative:	CMC Medical Devices & Drugs S.L. Horacio Lengo Nº 18, CP 29006, Málaga, Spain
SRN:	/
Product Name:	Disposable vinyl exam glove S, M, L, XL.
GMDN Code:	Non-powdered: 47176, Powdered: 47177.
UMDN Code:	11882
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.
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, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO

Signature:

Name:	Liu Yanjin
Position:	General Manager
Place/date:	Jiujiang City, 2020-04-09

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