

# 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 N° 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:

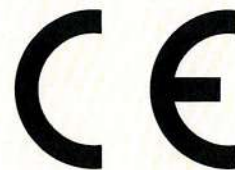
Regulation (EU) 2017/745 of the European Parliament and of the Council of  
5 April 2017 on medical devices, amending Directive 2001/83/EC,  
Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and  
repealing Council Directives 90/385/EEC and 93/42/EEC.

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



File No.: JXPL/CE01-01-06, ver.A/0

