



## Zhonghong Pulin Medical Products Co.,Ltd.

Add: West Industrial Park, Luannan County, Tangshan City, 063500,  
Hebei, China

Tel:0086-315-4167693 Fax:0086-315-4168700

### Declaration of Conformity

Manufacturer: Zhonghong Pulin Medical Products Co.,Ltd.

Address: West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China

SRN: CN-MF-000001108

European Representative: Lotus NL B.V.

Address: Koningin Julianaplein10, 1e Verde, 2595AA, the Hague, Netherlands

SRN: NL-AR-000000121

Product Name: Disposable Medical Nitrile Exam Glove

XS, S, M, L, XL.

Colors: Blue and Black

Type: Powder Free, Non-Sterile

GMDN Code: 56286

UMDN Code: 11882

Basic UDI-DI: 697040580ZHPFN02XY

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. 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 15223-1:2016 | EN 1041:2008 | EN ISO 14971:2019 | EN 62366-1:2015+AC:2015 | ISO 10993-1:2018 | ISO 10993-10:2010 | ASTM D4169-2016 | ISO 188:2011 | ISO 21171:2006 | ASTM D6319-19 | ASTM D5151-06 (2015) | ASTM D6124-06 (2017) | ASTM D7160-16 | MDCG 2019-15 | EN ISO 20417:2021

中红普林医疗用品股份有限公司  
Zhonghong Pulin Medical Products Co., Ltd.

Signature:

Date:

29 March 2022