EU Declaration of Conformity

Manufacturer:	Zhonghong Pulin Medical Products Co.,Ltd. West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China
SRN:	CN-MF-000001108
European Representative:	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
SRN:	NL-AR-000000121
Product Name:	Disposable medical nitrile exam glove XS, S, M, L, XL.
GMDN Code:	56286
UMDN Code:	11882
Basic UDI:	697040580ZHPFN02XY

Digitally signed by Guțan Ghenadie
Date: 2021.09.11 10:59:08 EEST
Reason: MoldSign Signature
Location: Moldova

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 10993-5:2009, 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

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Signature:	
Name:	Yang Yongling
Position:	General Manager
Place/date	Tangshan City, 2020-02-21