



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

EU 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 Lotus NL B.V
Representative: koningin Julianaplein10, 1e Verd, 2595AA The Hague, Netherlands
SRN: NL-AR-000000121
Product: Disposable Medical nitrile exam glove
X-Small, Small, Medium, Large, X-Large
GMDN Code: 56286
UMDN Code: 11882
Basic UDI: 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 de products ZHPFN02 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

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

Signature:

Date:

July 06, 2021