

EU Declaration of Conformity

Company name: Prenger Healthcare B.V.
Lange Kleiweg 14
2288 GK, Rijswijk, The Netherlands

Manufacturer: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County
Tangshan City 063500, Hebei, China

European Representative: Lotus NL B.V.
Koningin Julianaplein 10, first floor
2595 AA, The Hague, The Netherlands

Object of declaration: Prenger 1001 Disposable Nitrile Gloves 3.5G Blue
Model: 1001
Intended purpose: Nitrile Examination Gloves intended to be worn by healthcare practitioners to protect patient and user from cross-contamination.
GMDN code: 56286
UMDNS 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.

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, ISO10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM 04169-2016, ISO188:2011, ISO 21171:2006, ASTM 06319-19, ASTM 05151-06(2015), ASTM D6124-06(2017), ASTM D7/160-16, MDCG 2019-15.

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.

Prenger Healthcare B.V.:
Name: Mr. Peter Prenger
Title: Founder
Signature:

Zhonghong Pulin Medical Products Co., Ltd.:
Name: Mr. Shi Da
Title: General Manager
Signature:

Place, date: 1-1-2022

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