

# 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

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**Object of declaration:** Prenger 1010 Disposable Vinyl Examination Gloves 4.0G Transparant  
**Model:** 1010  
**Intended purpose:** Vinyl Examination Gloves intended to be worn by healthcare practitioners to protect patient and user from cross-contamination.  
**GMDN code:** Non-powdered: 47176, Powered: 47177  
**UMDNS code:** 11882  
**Basic UDI:** 697040580ZHPFV01Z6

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 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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