

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

SRN CN-MF-000001108

Authorised representative Lotus NL B.V
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SRN NL-AR-000000121

The EU declaration of conformity is issued under the sole responsibility of the manufacturer

Product / device name Nitrile examination gloves, Non-sterile, Latex free, Powder free
NG002x, NG008x, x= size XS, S, M, L, XL Color: Blue
NG005x, x= size XS, S, M, L, XL Color: Black
GMDN Code: 56286. UMDN Code: 11882

Intended purpose Disposable protective nitrile gloves providing a barrier against potentially biological agents, chemical substances and other contaminants

Basic UDI-DI 697040580ZHPFN02XY

The devices covered by present declaration is in conformity with EU Regulation 2017/745 on medical devices

Risk class Medical device, Class I, Rule 1. In accordance with the rules set out in Annex VIII

Standard conformity EN455-1:2020, EN455-2:2015, EN455-3:2015, EN455-4:2009

Conformity assessment Annex II, Annex III, Article 19

The devices covered by present declaration is in conformity with EU Regulation 2016/425 on personal protective equipment

Category PPE, Cat III

Standard conformity EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, EN ISO 21420:2020

Module B Certificate No: 2777/18208-01/E00-00
Issued by Notifying Body: SATRA Technology Europe Ltd (2777)
Bracetown Business Park, Clonee, D15 YN2P, Ireland

Conformity assessment Annual compliance testing of selected samples by the Notifying Body:

Module C2 SATRA Technology Europe Ltd (2777)
Bracetown Business Park, Clonee, D15 YN2P, Ireland

Place Beijing, China

Date of issue 24/06/2022

Name and function Shawn Su, Deputy General Manager

Signature on behalf of Zhonghong Pulin Medical Products Co., Ltd.