

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, XXL.

Classification: PPE Category III.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the
Regulation (EU) 2016/425 for personal protective equipment.

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.

Applied standards, common specification, guidance:

EN ISO201420:2020 EN ISO374-1:2016+A1:2018 EN ISO374-2:2019
EN ISO374-4:2019 EN ISO374-5:2016 EN 16523-1:2015+A1:2018

Notified body: TUV Rheinland LGA Products GmbH - 90431 Nurnberg
Notified body number: 0197
Certificate No.: BP 60137453 Sheet 0001

Application for: EU-Konformitaet PSA, MODUL C2
Certificate no.: QP 60157659 Sheet 0001

The subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals(Module C2) under surveillance of the notified body TUV Rheinland LGA Products GmbH(CE 0197).

Product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation(EU) 2016/425 as a Category III product.

Signature:

Name:

Yang Yongling

Position:

General Manager

Place/date

Tangshan City, 2020-02-21