

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Zhonghong Pulin Medical Products Co.,Ltd.
Address: 35 Songhe Ave, Luannan County, Tangshan
City, Hebei Province 063500

EU Representative

Name: Lotus NL B.V
Address: Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.

Products, type, batch or serial number :

Product name: Nitrile Examination Gloves, Category III, Class I

Vinyl Examination Gloves, Category III, Class I

Style No. : NG145 (Annex I)

Conformity Assessment Route: Annex I according to the provisions of Regulation(EU)2016/425 of 9 March 2016,Regulation(EU)2017/745 of 5 April 2017.

Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

The manufacturer declares that the personal protective equipment (PPE) described above is in conformity with the provisions of Regulation(EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment, and conformity with the requirements of above regulation is testified by complete adherence to the following technical specifications: EN ISO 374-1+A1:2018 and EN ISO 374-5: 2016 Protective gloves against dangerous chemical and micro-organisms.

The manufacturer also declares that the products described above is in conformity with the provisions of 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

Zhonghong Pulin Medical Products Co.,Ltd



Signed by: Zhisheng Su

Position: General Manager

Date: 08/01/2022

Annex I

Product Code	Description	Color	Samples quantity (Pcs)
101	Nitrile gloves, Powder-free non sterile, 3.0 g, AQL 1.5, medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Blue/Black/White/Purple	10
102	Nitrile gloves, Powder-free non sterile, 3.5 g, AQL 1.5, medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Blue/Black/White/Purple	10
103	Nitrile gloves, Powder-free non sterile, 4.0 g, AQL 1.5, medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Blue/Black/White/Purple	10
104	Nitrile gloves, Powder-free non sterile, 4.2 g, AQL 1.5, medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Blue/Black/White/Purple	10
105	Nitrile gloves, Powder-free non sterile, 5.0g, AQL 2.5/4, medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Blue/Black/White/Purple	10
106	Nitrile gloves, Powder-free non sterile, 5.5g, AQL 2.5/4, medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Blue/Black	10
107	Nitri-tec Vinyl(Nitrile Blended), Powder-free non sterile, 5.2g medical device class I with EN 455 and EN 374. XS/S/M/L/XL/XXL	Blue	10
108	Vinyl gloves ,Powder-free non sterile ,4.0g. medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Clear/Blue	10
109	Vinyl gloves ,Powder-free non sterile ,4.5g. medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Clear/Blue	10
110	Vinyl gloves ,Powder-free non sterile ,5.0g. medical device class I, with EN 455 and EN 374. XS/S/M/L/XL/XXL	Clear/Blue	10