Zhonghong Pulin Medical Products Co., Ltd.

EU Declaration of Conformity

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

Koningin Julianaplein 10,1e Verd, 2595AA, The Hauge, Netherlands

SRN: NL-AR-000000121

The manufacturer hereby declare under our responsibility that the specified product(s) conforms with all requirements in/under the regulation and standards in the European Union(EU) which applies to the product.

The specified product(s)are therefore labelled with the CE marking:

Product name	Product number	Product Description
Nitrile Examination Gloves	ZHPFN02	Protective gloves, chemical risks. Medical device, for single use Food contact Size:XS,S,M,L,XL,XXL GMDN Code:56286

Basic UDI-DI
697040580ZHPFNO2XY

Risk classification / categorisation
Medical device, class I
Personal protective equipment (PPE), category IIII

The product is in conformity with the following European Regulation:

Regulation number	Regulation name
2017/745	Regulation (EU) of the European Parliament and of the Council of 5.April 2017 on medical devices
2016/425	Regulation (EU) of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment

The product is in conformity with the following Union harmonized standards:

Standard number	Standard name
EN ISO 374-1: 2016 +A1:2018 EN ISO 374-2:2014 EN ISO 374-4:2013 EN ISO 374-5:2016 EN 16523-1: 2015+A1:2018	Protective gloves against dangerous chemicals and micro-organisms
EN 420:2003 +A1:2009	Protective gloves - General requirements and test methods
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Medical gloves for single use
ISO 188:2011	Rubber, vulcanized or thermoplastic-Accelerated ageing and heat resistance tests
ISO 21171:2006	Medical gloves-Determination of removable surface powder
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010	Biological evaluation of medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical devices- Application of risk management to medical devices
EN 62366-1:2015+AC:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices-Quality management systems
Resolution ResAP (2004)4	Food Contact Material-Rubber

The product is in conformity with the following common specifications (CS):

CS	
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Notified Body responsible for certification and ongoing conformity :

SATRA Technology Europe Ltd

Bracetown Business Park

Clonee, Dublin, D15 YN2P, Ireland (Notified Body: 2777)

performed the EU-type-examination (Module B) and issued the EU type-examination certificate:

Certificate No.: 2777/18208-02/E00-00

Date: 27/10/2022

Expiry Date: 26/8/2026

The PPE is subject to the conformity assessment procedure (Module C2 /Module D)under surveillance of the above mentioned notified body.

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This declaration of conformity is issued under the sole responsibilty of the manufacturer.Signed for and on behalf of

Zhonghong Pulin Medical Products Co., Ltd.

Zhao Enyou

General Manager

China, 31/10/2022