ZHONGHONG PULIN MEDICAL PRODUCTS CO., LTD

West Industrial Park, Luannan County, Tangshan City, Hebei, China 063500

Declaration of Conformity

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

UK/EC Authorised Representative:
MedPath Limited
27 Old Gloucester Street, London, United Kingdom, WC1N 3AX

Brand/Model: Z/Z

Product Reference: ZHPFN02, ZHPFN04
Product: Nitrile Gloves, Powder Free
The materials, specification and manufacturing process for the blue nitrile gloves (ZHPFN02) and the black nitrile gloves (ZHPFN04) are identical, and they only differ in colour.

Sizes: Small, Medium, Large, X-Large

Risk Classification: Medical Device, Class I; PPE, Category III

GMDN Code: 56286

UMDN Code: 11882

Basic UDI: 697040580ZHPFN02XY

We, Zhonghong Pulin Medical Products Co.,Ltd, herewith declare under our sole responsibility as the manufacturer that the above-mentioned products are in full compliance and conformity with the following Manufacturing Processes, European Regulations and Union Harmonized Standards

The product is in conformity with the following Manufacturing Processes:

Regulation number	Regulation name
EN ISO 9001:2015	The gloves are manufactured according to ISO 9001:2015 Quality Management Systems, as certified by CQC.
EN ISO 13485:2016	The gloves are manufactured according to ISO 13485:2016 Quality Management Systems. Specific for Medical Devices, as certified by Notified Body, TUV Rheinland.

The product is in conformity with the following European Regulations:

Regulation number	Regulation name
Annex VIII of the Medical Device Regulation (EU) 2017/745	Regulation (EU) of the European Parliament and of the Council of 5. April 2017 on medical devices, with reference to the harmonized standard, EN455-l, EN455-2, EN455-3 and EN455-4 and is self-certified as a Class I non-sterile medical device.
European Medical Device Directive 93/42/EEC	Medical Devices Regulations 2002, UK Statutory Instruments 2002 No. 618, as amended, for Class I medical Devices.
Personal Protective Equipment (PPE)-Regulation (EU) 2016/425	Regulation (EU) of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment, Module C2 as a Category III product, and the requirement of the European harmonized standard EN ISO 21420:2020 & EN374 Parts 1/2/4/5. This has been certified by Notified Body CE 0197, TUV Rheinland, Germany.

The product is in conformity with the following Union Harmonized Standards:

Standard number	Standard name
EN ISO 21420:2020	Protective gloves - General requirements and test methods.
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Parts 1-4: Medical gloves for single use.
EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 374-4:2013, EN ISO 374-5:2016	Part 1: Protective gloves against dangerous chemicals, Type C, K Part 2: Resistance to Penetration: Air & Water Part 4: Resistance to Degradation by Chemicals Part 5: Protective gloves against micro-organisms (Virus)
EN 1186:2002	Food Migration – Materials and articles in contact with food stuffs.
ISO 10993-5:2009	Biological evaluation of medical devices

ZHONGHONG PULIN MEDICAL PRODUCTS CO., LTD

Signature:

Name: Zhisheng Su

Title: General manager

Date: 07/21/2021