

Zhonghong Pulin Medical Products Co., Ltd

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

Tel:0086-315-4167693 Fax:0086-315-4168700

EU MEDICAL DEVICE DECLARATION OF CONFORMITY

We, undersigned, hereby declare that the disposable device(s) specified below under our sole responsibility meet the provisions of Regulation (EU) 2017/745 on Medical Devices.

Manufacturer: Zhonghong Pulin Medical Products Co., Ltd
West Industrial Park, Luannan County,
Thangshan City
Hebei Province, China
Tel: 0086-315-4167693 Fax: 0086-315-4168700

SRN: CN-MF-000001108

EU Authorized Representative: Continental Medical BV
2F John M. Keynesplein 1-27
Amsterdam 1066EP Netherlands

SRN: NL-AR-000022261

Product: Nitrile Examination Gloves Powder Free, Blue

Model and Description: PD-NT-PWF-S
PD-NT-PWF-M
PD-NT-PWF-L
PD-NT-PWF-XL

GMDN Code: 56286
UMDN Code: 11882
Basic UDI : 697040580ZHPFN02XY

Classification: classification (MDR, Annex VIII): Classe 1, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II+Annex III+Article 19 of MDR(EU) 2017/745.

The object of the declaration described is in conformity with the

| Relevant EU harmonization legislation: | And European Standards: |
|--|--|
| Regulation (EU) 2017/745 on Medical Devices | EN 455-1:2020 EN 455-2:2015 EN 455-3: 2015 EN 455-4: 2009 EN ISO 13485:2016 EN ISO 21420:2020 |

Name: ZHAO Enyou
Position: General Manager
Place:Tangshan
Date:08/01/2024

