

## Zhonghong Pulin Medical Products Co., Ltd

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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, Black

Model and Description: PD-BLACK/S  
PD-BLACK/M  
PD-BLACK/L  
PD-BLACK/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

