

EU Declaration of Conformity

Legal Manufacturer

Name Address Phone / fax / email / webpage	Zhonghong Pulin Medical Products Co., Ltd. West Industrial Park, BDA, Luannan, Tangshan, 063500 Hebei, China	www.zhonghongpulin.cn Phone: 86-10-67890877 Fax: 86-315-4168700 sales@zhonghongpulin.cn
Single Registration Number (SRN), if applicable	CN-MF-000001108	
Authorized European Representative Name /Address	Continental Medical B.V. 2F John M. Keynesplein 1-27 Amsterdam 1066EP Netherlands NL-AR-000022261	

Medical Device(s)

Basic UDI-DI	697040580ZHPFN02XY
Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Nitrile Examination Gloves, Powder-free ZHPFN02
Other ref. allowing identification	GMDN Code: 56286 UMDN Code: 11882
Intended Purpose	Nitrile Examination gloves are intended to be worn by healthcare practitioners to protect patient and user from cross-contamination.
Risk classification	Class 1 according to rule no. 1 and 5 in MDR annex VIII

Other information

Notified Body Name and identification number	SATRA Technology Europe Limited Bracetown Business Park, Clonee D15YN2P, Republic of Ireland (2777)
EU type examination certificate number	2777/18208-02/E00-00
Assessment procedure	Module B. Module D,

The above mention manufacturer hereby declare that the above mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under “additional information”.

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function: Xin Guo, Product Manager	
Signature 	Place and date of issue Beijing, China, 3 rd Jan 2023
West Industrial Park, BDA, Luannan, Tangshan, 063500 Hebei, P.R. China	

Appendix I, List of applicable standards used

Product Name	Standards used
Nitrile Examination gloves, powder free	EN 455-1: 2020
Nitrile Examination gloves, powder free	EN 455-2: 2015
Nitrile Examination gloves, powder free	EN 455-3: 2015
Nitrile Examination gloves, powder free	EN 455-4:2009

Date: 3rd Jan 2023