# EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

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|---|---|
| Manufacturer: | Name: Changzhou Xingrong Medical Technology Co. LTD<br>Add: No. 528, Daqiaotou, Chaoyang Cunwei, Hengshanqiao Town, Economic Development District, 213119 Changzhou, Jiangsu, China |
| Trade name / Trademark: | ZinRom |
| SRN: | Not available yet |
| European Representative: | Name: MedPath GmbH<br>Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany |
| SRN: | DE-AR-000000087 |
| Product Name: | DISPOSABLE NITRILE EXAMINATION GLOVES |
| Trade name: | N.A. |
| Product size: | XS, S, M, L, XL |
| Basic UDI: | Not available yet |
| UMDNS Code: | 11-882 |
| Classification acc. to MDR Ax. VIII: | Class I, Rule 5 |
| Applied Common Specification/ standard: | ENISO13485:2016 / EN 455-1:2020 / EN 455-2:2015<br>EN 455-3:2015 / EN 455-4:2009 / EN ISO14971:2019<br>ISO10993-1:2018 / ENISO10993-5:2009 / ENISO10993-10:2013<br>EN1041:2008/A1:2013 / ENISO 15223-1:2016 / ISO 11193-1: 2008 |
| Conformity assessment procedure: | MDR Annex II + Annex III |
| CE certificate No. : | N.A. |
| Name/address of the Notified Body: | N.A. |
| ID of the Notified Body: | N.A. |

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Place of Issue: Changzhou, Jiangsu, China

Date of Issue: 2021-01-25

Signature:

Mr. Zhou Jianrong

Position: General Manager