



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN 13795-2:2019

Remark

The declaration of conformity is valid in connection with the release technical document HNZH-MDR-02-02.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Hunan Zhenheyikang Medical Instrument Co.,Ltd
Address: NO.6 Building Jingxiang Energy, No.55 Xianguang east road, Gaoxin district Xiangtan, Hunan
SRN: CN-MF-000008403

Product Information

Name: Disposable Protective Coveralls
Model: S, M, L, XL, XXL, XXXL
GMDN: 58390
Basic UDI-DI: /
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2021. 7. 28

POSITION: GM

PLACE: Hunan/China