



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
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 1041: 2008
EN 14683 : 2019

Remark

The declaration of conformity is valid in connection with the release technical document HNZH-MDR-01-02.

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 Face Mask
Model : 175*95mm, 145*90mm, 16.0*10.0cm, ear hook type, tie on type
GMDN: 35177
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: 2024.7.28

Position: GM

Place: Hunan/China

