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: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 455-1:2020
EN 455-2:2015
EN455-3:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-CJ-03.

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: SHANGHAI CHONGJEN INDUSTRY CO.,LTD.
Address: Room 402,Building 37,No.258 Xinzhuan Road,Caohejing Hi-tech Park,Songjiang District,Shanghai,China.

Product Information

Name: Disposable vitrile gloves
Model: S/M/L/XL
GMDN: 56286
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: 2021.04.29

Position: GM Place:Shanghai/China