



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 62366-1: 2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-10.

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

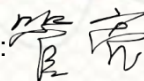
Name: WUXI EMSRUN TECHNOLOGY CO.,LTD
Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

Product Information

Name: Scissors
Model: 5cm,10cm,12cm,14cm,15cm,16cm,19cm
GMDN: 13481
Basic UDI-DI: 6974567745cmXX
Classification: Class I
SRN: CN-MF-000008968
Intended use: Scissors is a type of scissors used by paramedics and other emergency medical personnel to quickly and safely cut out tape or bandage.

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: 2021.09.30



Position: GM

Place: WUXI, CHINA