



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert GmbH
Harffstr. 47, 40591 Düsseldorf, Germany
SRN: DE-AR-000010869

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-L01040199-23.

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: EMSRUN GROUP
Address: 8-7 Huide Road, Huishan Area, Wuxi, 214000 Jiangsu, P.R. China
SRN: CN-MF-000037456

Product Information

Name: SCISSORS
Model: Buckle, Non-buckle, Multifunctional
Size: 5cm, 9cm, 10cm, 12cm, 13cm, 14cm, 15cm, 16cm, 16.5cm, 18.5cm, 19cm
EMDN: L01040199
Basic UDI-DI: 697567578SI01UG
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Function: intend use (for example) 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: 2024.10.11

Position: PRRC

Place: Jiangsu/China

