



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: 2021
EN ISO 20417: 2021
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-24.

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: Chest Seal
Model: CR-CS01
GMDN:
Basic UDI-DI: 697456774CR-CS01TR
Classification: Class I
SRN: CN-MF-000008968
Intended use: Chest Seal is suitable for First-Aid hemostasis and trauma nursing.Composed of Outer package bag, chest seal.

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

