



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522,
Unit 1.7, 2909VA Capelle aan
den IJssel, The Netherlands

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 ISO 20471:2021
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-09.

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: Emergency blanket

Model: CR-080


GMDN: 10416

Classification: Class I

Intended purpose: The Emergency blanket is also called survival blanket, thermal blanket. The aluminized layer could reflect more than 90% of your body heat, to keep your body warm under emergency situation. It is an essential goods using outdoor especially in hiking, camping,and wilderness survival.

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