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

Manufacturer

Name: WUXI EMSRUN TECHNOLOGY CO.,LTD

Address: No.100 Fengbin Road,WUXI city,JIANGSU province,China

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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-29.

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.

Product Information

Name: Aluminum Moldable Splint

Model: CR-06

GMDN: M03050299

Basic UDI-DI: 697456774CR-06KV

Classification: Class I

Intended purpose: The Aluminum Moldable Splint is intended to be used to support and fix the injured limbs like finger, neck, arm and so on.

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