



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
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## 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-14.*

*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:** Ambulance stretcher

**Model:**CR-10, CR-11, CR-12, CR-13, CR-14, CR-15, CR-16, CR-17, CR-18, CR-21

**GMDN:** 35843

**Basic UDI-DI:** 697456774CR-11KN

**Classification:** Class I

**Intend Purpose:** Ambulance stretcher is used to be equipped in ambulance or to be applied as general stretchers to transport patients in emergency centers

## 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

