



# 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: 2016  
EN 1041:2008+A1:2013  
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-10.*

*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

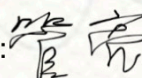
**Name:** WUXI EMSRUN TECHNOLOGY CO.,LTD  
**Address:** No.100 Fengbin Road,WUXI city,JIANGSU province,China

## Product Information

**Name:** Scissors  
**Model:** 5cm,10cm,12cm,14cm,15cm,16cm,19cm  
**GMDN:** 13481  
**Basic UDI-DI:** 6974567745cmXX  
**Classification:** Class I  
**SRN:** CN-MF-000008968  
**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: 2021.09.30



Position: GM

Place: WUXI, CHINA