



# 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: 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-CS05

**GMDN:** 47917

**Basic UDI-DI:** 697456774CR-CS01TR

**Classification:** Class I

**SRN:** CN-MF-000008968

**Intended purpose:** 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

