



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: WUXI EMSRUN TECHNOLOGY CO.,LTD

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

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam,Netherlands

Product Name: Chest Seal

Model: CR-CS01

SRN: CN-MF-000008968

Basic UDI-DI: 697456774CR-CS01TR

Classification: Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2012

EN ISO 15223-1: 2016

EN 1041:2008+A1:2013

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

Signature: 

Name/ Position: Guan Liang/ C

Date: 2020.9.23

Place: Jiangsu / China



