DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

CE

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: 2016 EN ISO 20471:2021 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-08. 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: Tape Model: CR-AT01(CR-AT16) GMDN: 58986 Basic UDI-DI: 697456774CR-AT01TG Classification: Class I Intended Purpose: Medic tape to assist and provide additional security and support to bandages

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. The Date:2021.09



Position: GM