



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: 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

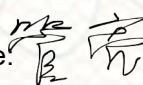
Basic UDI-DI: 697456774CR-AT01TG

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: 

Date:2021.09.30



Position: GM

Place:WUXI CHINA