



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

ENISO14971:2019
EN ISO 20471:2021
ENISO10993-5:2009
ENISO15223-1:2016
ISO10993-1:2018
ENISO10993-10:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-01.

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: Mouth-to-mouth face mask

GMDN: 13818

Model: CR-CPR06

Basic UDI-DI: 697456774CR-PP01W5

Classification: Class I

Intended Purpose: Oxygen mask that helps deliver oxygen in emergency situations.

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

