

MD

DECLARATION OF CONFORMITY

ACCORDING TO MEDICAL DEVICES ORDINANCE OF 1 JULY 2020

CH Representative

Name: SUNGO Technical Service GmbH
Address: Bahnhofstrasse 21,6300 Zug,
Switzerland
SRN: CHRN-AR-20002937

Conformity Assessment

Conformity Assessment Procedure

Section 1, Chapter 3 of Medical Devices
Ordinance of 1 July 2020

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2021
EN ISO 20417:2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023
EN ISO 10993-23:2021

Remark

*The declaration of conformity is valid in connection
with the release technical document*

CH/MEDDO-NC-04.

*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

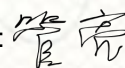
Name: Wuxi EMSRUN Technology Co.,Ltd.
Address: 2002-2004 Suning Buliding, Liangxi
area, Wuxi city, 214000, China
SRN: CN-MF-000008968

Product Information

Name: Gloves
Model: S,M,L,XL
EMDN: T0102
Classification:
Class I, According to Section2, Chapter2 of Medical
Devices Ordinance of 1 July 2020

Declaration

We herewith declare that the above-mentioned
products meet the requirements of Medical Devices
Ordinance of 1 July 2020 and the applicable
standards above.

Signature: 

Date: 2023.12.21

Position: GM

Place: Wuxi / China

