



# 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  
EN 455-1:2020  
EN 62366-1:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-21.*

*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:** Gloves (Medium/Large/X-Large)

**Model:**CR-GV02,CR-GV03 , CR-GV04

**GMDN:** 56286

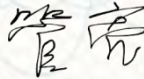
**Basic UDI-DI:** 697456774CR-GV01V4

**Classification:** Class I

**Intended Purpose:** To use blue color gloves to easily recognize blood on gloves when sweeping a patient

## 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

