



# 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 ISO 10993-1:2020  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN 166 : 2001

### 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:** EYE SHIELD

**Model:** CR-EP01-2

**EMDN:** T0399

**GMDN:** 58376

**Basic UDI-DI:** 697456774CR-EP01TQ

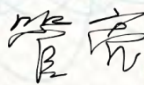
**UDI:** 06974567743486

**Classification:** Class I, According ro Rule 1, Annex VIII, Regulation(EU) 2017/745

**Intended Purpose:** To prevent eyes to be hurted again during movement

## 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

