# DECLARATION OF CONFORMITY

**ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION**

## EU Representative

**SUNGO Europe B.V.**
**Olympisch Stadion 24, 1076DE**
**Amsterdam, Netherlands**
**SRN: NL-AR-000000247**

## 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 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

**Remark**

*The declaration of conformity is valid in connection with the release technical document CE/MDR-SD-02.*

*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:** WENZHOU SHENGDING INDUSTRY & TRADE CO.,LTD
**Address:** **#C6,zhihui industry zone, #66,tingchao road , shangwang block,Ruian ,Wenzhou city ,zhejiang province ,china**
**TEL: 0086-13566278618**

## Product Information

**Name : TOURNIQUET**
**Model : KT-GF03**
**GMDN :** 58128
**Basic UDI-DI :** /
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

## 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:2021/5/31

Position: GM Place: Zhejiang/China