DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer: SHENZHEN TMI MEDICAL SUPPLIES CO., LTD.

Address: Floor 4th, Block 1, the second industrial zone, HuangMabu of Bao'an district, Shenzhen, China.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Tourniquet

SRN: /

Basic UDI-DI: /

Classification Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2012

EN ISO 15223-1: 2016

EN 1041:2008+A1:2013

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Signature:

Name / Position: Zhang Zubiao / General Manager

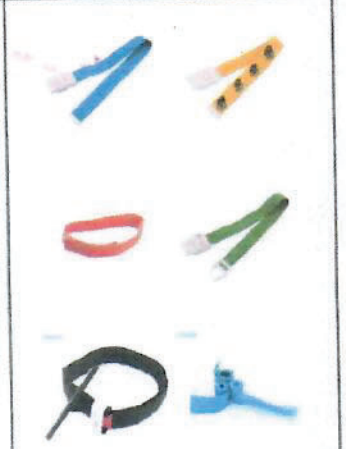
Sungo global service

Authorized Signature (S)

Date: 2020.12.10

Place: ShenZhen / China

Annex

Product	Model	Basic UDI-DI	Picture
Tourniquet	TM-A001, TM-A002, TM-A003, TM-A004, TM-B001, TM-B002	/	

Signature:

Name / Position: Zhang Zubiao / General Manager

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