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: 张祖标

Name / Position: Zhang Zubiao / General Manager

Sungo

Authorized Signature (S)

Date: 2020.12.10

Place: ShenZhen / China