

EU DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION



Manufacturer

Name: RUIAN SUNNYWORLD
INTERNATIONAL TRADE CO.,LTD.

Address: No.3, Sanxiang, Gaoyang Road,
Ruian city, Zhejiang Province, China

EU Representative

Luxus Lebenswelt GmbH [DE]

Kochstr 1, Willich,
Germany, 47877

Product information

Name: TOURNIQUET

Model: SW-GT01, SW-GT03, SW-GT04,SW-GT05,SW-GT06,SW-GT08,SW-GT14,
SW-GT18,SW-GT19,SW-GT26

GMDN: 35844

Basic UDI: 697278932TOU009YC

SRN: /

Classification: Class I

For and on behalf of



LUXUS LEBENSWELT GMBH
Kochstr.1, 47877 Willich, Germany

Only used for EU Representative Agreements

Conformity Assessment

Conformity Assessment Procedure:

Annex II+III of Regulation (EU) 2017/745

Applicable Standards:

EN ISO14971:2019; EN ISO15223-1:2016; EN1041:2016; ISO10993-5:2009;
ISO10993-10:2010

Declaration

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

The EU Declaration of Conformity is issued under the sole responsibility of the
manufacturer.

Place: Ruian/China

Date: 2022.05.01

Signature:

Position: GM

