



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Caretechion GmbH
Niederrheinstr. 71, 40474
Düsseldorf, Germany
SRN: DE-AR-000005946

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
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-TPS-03.
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: HANGZHOU TUOPUSI MEDICAL PRODUCTS CO.LTD
Address: Room 606, Mutouqiao 8-36, Donglian villiage, Liangzhu Street,Yuhang District, Hangzhou City,Zhejiang,China .PC:311112
SRN:CN-MF-000039733

Product Information

Name: Triangular Bandage
Model: TPS NTB01,NR72-VSDT-BWO-01
GMDN: 10274
Basic UDI-DI: 697714346TPSBB016L
Classification: Class I
Intended use: The device is intended for securing wound dressings and splints or for providing mild compression or support. The device can also be used as an arm sling.

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: Jason Wu
Name: Jason Wu
Position: PRRC



Date: 2024.12.02
Place: HANGZHOU, CHINA