



NINGBO HI-TECH UNICMED IMP. & EXP. CO., LTD

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EU Declaration of Conformity

Manufacturer:

Name: Ningbo Hi-Tech Unicmed Imp. & Exp. Co., Ltd.
Add: 11/F, Green Town Lvyuan Tower, No.588 Canghai Road,
Ningbo, China

European Representative:

Name: Shanghai International Holding Corp. GmbH(Europe)
Add: Eiffestrasse 80.20537 Hamburg, Germany

Product Name: Tourniquet

Trade name /Trademark: N.A.

Model: TPE

SRN: Not yet

UMDNS Code: 58128

Basic UDI-DI: 6974495690804015R

Classification (MDR, Annex VIII): I, rule 1

Conformity Assessment Route: Annex II and III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU)2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

REGULATIONS

General applicable regulations:

Medical Device Regulation: REGULATION (EU) 2017/745

Place of Issue: Ningbo, CHINA

Date of Issue: 2021-06-04

Signature: Mr. Honghao Zhou

Position: General Manager

