



EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: GAUKE Healthcare Co., Ltd.

No. 82, TuanFeng Avenue, TuanFeng Town, TuanFeng, Huang Gang City, Hubei Province, 438800, P.R. China.

Trademark:



SRN: CN-MF-000013784

European Representative: MedPath GmbH

Mies-van-der-Rohe-Strasse8 80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: Tourniquet

Product name: Tourniquet

Intended useIt is intended to bind and compress the limb of bodies

to stop bleeding.

Basic UDI: 69514547318VH

Classification acc. to MDR Ax. VIII: Class I, Rule 1

Applied Standard & Common

Specification:

ISO 13485-2016

Conformity assessment procedure: Annex II + Annex III of MDR

CE certificate No.: N.A.

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.

Name and function:

Maltew shang

Mattew Zhang / Genera Manager

Place, date:

Huanggang, 21. 04. 2022