

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:



GAUKE[®]

SRN:

CN-MF-000013784

European Representative:

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

SRN:

DE-AR-000000087

Trade name:

STERILE BANDAGES TNT DIN13152

Product name:

STERILE BANDAGES TNT DIN13152

Intended Use:

Indicated in the case of abrasions and burns.

Basic UDI:

Not available yet
Class I, Rule 4

Classification acc. to MDR Ax. VIII:

**Applied Standard & Common
Specification:**

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.

Johnny Sui

Name and function :
Johnny Sui / General manager

Place, date:
Huanggang, 24. 09. 2021

