

EU DECLARATION OF CONFORMITY

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

Manufacturer: GAUKE Healthcare Co., Ltd
No.8,Jiangbei Highway,TuanFeng Town,TuanFeng ,
Huang Gang City, Hubei , 438800, China.

SRN: CN-MF-000013784

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich,
Germany

SRN: DE-AR-000000087

Trade name: First Aid Dressing Bandage

Product name: First Aid Dressing Bandage

Intended Use: It is intended for non-chronic wound care, or for
wound dressings or limbs to provide binding force, to
play a binding, fixed role. This product can be loaded
into various first aid kits for emergency rescue of the
wounded by ambulance personnel at the scene of
injury.

Basic UDI-DI: 69514547300UW

Classification acc. to MDR Ax. VIII: Class Is, Rule 4

**Applied Standard & Common
Specification:** EN ISO13485:2106

Conformity assessment procedure: MDR Annex IX Chapter I and III

CE certificate No.: MDR 732347 R001

Notified Body: BSI Group The Netherlands B.V., Say Building, John
M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands,
CE2797

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.

Matthew Zhang

Name and function :
Matthew Zhang / General manager

Place, date:
Huanggang, 2026.2.12

