

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:

Bandage 4X8 cm

Product name:

Bandages

Intended Use:

It is intended to provide compression for wound dressing or limbs to play a binding and fixing role.

Basic UDI:

69514547300UW

Classification acc. to MDR Ax. VIII:

Class I

Applied Standard & Common Specification:

DIN 61634

Conformity assessment procedure:

MDR Annex IX Chapter I and III

CE certificate No.:

MDR 732347 R000

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, 21. 04. 2022

