

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-Strasse8
80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: Sterile Absorbent Gauze Dressing

Product name: Sterile Absorbent Gauze Dressing

Intended Use: It is intended to clean the skin or wound, absorb the exudate from the body during the operation, use it together with the commonly used drugs for wound care. The device is widely used in hospital, and it is disposable.

Basic UDI-DI: 69514547313V7

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

Applied Standard & Common Specification: EN ISO13485:2016

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

