

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: Disposable Medical Mask (Non-sterile)

Product name: Disposable Medical Mask (Non-sterile)

Intended Use: It is intended to protect the human body from harmful substances such as germs and viruses. It is mainly for protection and isolation.

Basic UDI-DI: 69514547309VG

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

Applied Standard & Common Specification: EN ISO13485:2016

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.

Matthew Zhang

Name and function :
Matthew Zhang / General manager

Place, date:
Huanggang, 2025.5.14

