

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:

Not available yet

European Representative:

MedPath GmbH

1 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:

69514547309VG

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

Applied Standard & Common Specification:

DIN 13129-2005

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. 02. 2021