

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
Mies-van-der-Rohe-Strasse8
80807 Munich, Germany

SRN:

DE-AR-000000087

Trade name:

CPR shield

Product name:

CPR shield

Intended use

It is intended to isolate the first-aid person and the injured person in the first aid and prevent the body fluid contact during mouth-to-mouth breathing.

Basic UDI:

Not available yet

Classification acc. to MDR Ax. VIII:

Class I, Rule 4

Applied Standard & Common Specification:

ISO 13485-2016

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.

Johnny Sui

Name and function :
Johnny Sui / General manager



Place, date:
Huanggang, 24. 02. 2021