



## **EU DECLARATIONOF 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

EuropeanRepresentative: MedPath GmbH

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

**SRN:** DE-AR-000000087

Trade name: Cleansing Wipe

Product name: Cleansing Wipe

**Intended Use:** It is intended to clean integrate skin, when the

integrate skin is contaminated by dirty soil, dirty

water or another rubbish.

**Basic UDI:** 69514547312V5

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

Applied Standard & Common ISO 13485-2016

Specification:

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.

Name and function:

Johnny Sui

Johnny Sui / General manager

Place, date:

Huanggang, 24. 02. 2021