

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: Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

SRN: ES-AR-000001202

Trade name: Alcohol Prep Pad

Product name: Alcohol Prep Pad

Intended Use: It is intended to clean and disinfect the integrate skin,
when the integrate skin is contaminated by dirty soil,
dirty water or another rubbish.

Basic UDI-DI: 69514547323VA

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, 2025.11.25