

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:



SRN:

Not available yet

European Representative:

Riomavix S.L.

Calle de Almansa 55, 1D, Madrid 28039 Spain

SRN:

ES-AR-000001202

Trade name:

Instant cold pack

Product name:

Instant cold pack

Intended Use:

Cold compress physiotherapy, only for closed soft
tissue.

Basic UDI:

69514547301UY

Classification acc. to MDR Ax. VIII:

Class I, Rule 1

**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