

OFFICIAL STATEMENT

According to Art. 22 of Regulation (EU) 2017/745 on Medical Devices

System/Procedure Pack

Producer:

SRN:

Systems / procedure packs:

Basic UDI-DI:

REF:

Composition:

GAUKE Healthcare Co., Ltd.

No. 82, TuanFeng Avenue, TuanFeng Town, TuanFeng ,
Huang Gang City, Hubei Province, 438800, P.R.China.

CN-PR-000038433

First Aid Kit DIN13164

69514547305V8

CPS685N

Components	quantity	Components	quantity
Adhesive bandage DIN 13019-E 10X6cm MD class I	1pcs	First aid dressing bandage DIN 13151 – K MD class Is	1pcs
Adhesive bandage 5.1 x 4.5 cm MD class I	1pcs	Absorbent non-woven compress 60x 80 cm DIN13152 – A MD class Is	1pcs
Adhesive bandage 12 cm x2cm MD class I	2pcs	Scissor DIN58279 –A145 MD class I	1pcs
Adhesive bandage 1.9 cm x7.2 cm MD class I	2pcs	First aid blanket 160x210 cm MD class I	1pcs
Adhesive bandage 2.5 cm x7.2 cm MD class I	2pcs	Cleansing wipe	1pcs
Adhesive tape 5 X2.5 cm DIN13019-A MD class I	1pcs	Disposable vinyl examination gloves DIN EN 455- 1 MD class I	2 pairs

In compliance with Article 22 of REG. UE 2017/745, declares that:

(a) We have verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and have carried out our activities in accordance with those instructions.

(b) We packaged the system / procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices and other products which have been put together;

(c) the activity of combining devices / other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

Matthew Zhang

Matthew Zhang
General manager



Huanggang, 01. 04. 2024