DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Caretechion GmbH

Niederrheinstraße 71

40474 Düsseldorf

Manufacturer

Name: Anji Hengfeng Sanitary Material Co.,Ltd.
Address: Ancheng, Dipu Town 313300
Anji County Zhejiang P.R China.

Sterilisation:

DD 60137855 0001 (TÜV Rheinland, 0169)
Effective date: 20190415
Expiration date: 20240323

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-24.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name: COMPRESSED GAUZE
Model: HFEB01 (Z-fold)
GMDN: 48131
Basic UDI-DI: 697151961HFEB01EU
Classification: Class Is
SRN: CN-MF-000008968
Intended purpose:

The compressed gauze is intended to be used to stop bleeding from wounds caused by injuries in pre-hospital emergency situations.

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date:2021.09.30

Position:GM Place: ANJI, CHINA