



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

Product Information

Name: Bandage

Model: HFFAB1-1

GMDN: 47011

Basic UDI-DI: 697151961HFFAB1GH

Classification: Class Is (Sterile)

SRN: CN-MF-000013051

Intended purpose: The Bandage is intended to be used to stop bleeding from wounds caused by injuries in pre-hospital emergency situations.

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.

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

