



EU DECLARATION OF CONFORMITY

ACCORDING TO ART. 19 OF REGULATION (EU) 2017/745 ON MEDICAL DEVICES

Name and address of the manufacturer: Anji Hengfeng Sanitary Material Co., Ltd
Ancheng, Dipu Town 313300 Anji County, Zhejiang,
China

SRN: CN-MF-000013051

Trademark: 

Name and address: Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, Germany,

SRN: DE-AR-000005946

Trade name: Sterile Bandage

Product name: Sterile Bandage

Product model: HF J-301...HF J-304; HF CG011; HF CG012; HF N101; HF N102; HF H103; HF H104

Intended Use: The Bandage is intended for securing wound dressings, I.V.'s and splints or for providing mild compression or support.

Basic UDI-DI: 697151961HFEB01EU

Classification according to MDR Ax. VIII: Class Is, rule 4

Applied standard: EN14079:2003, EN ISO 13485:2016/A11:2021; EN ISO 10993-1:2020; EN ISO 14971:2019; EN ISO 10993-12:2021; EN ISO 10993-23:2021; EN ISO 11137-1:2015/A2:2019; EN ISO 11137-2:2015; EN ISO 11737-1:2018/A1:2021; EN ISO 11737-2:2020; EN ISO 15223-1:2021

Conformity assessment procedure: Annex XI, part A

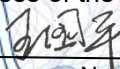
CE certificate no.: DZ 2111271-1

Name, address and ID of the Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Germany
CE 0197

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.

Anji, 2023.05.10

Place, date

 General manager

Name and function

Trade Secret, Confidential Documents

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