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 No.218, Liuguanli Road, Dipu Sub-district, Anji County, 313300 Zhejiang, P.R. China
SRN:	CN-MF-000013051
Trademark:	
Name and address c:	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 CH01; HF-CG012; HF N101; HF N102; HF N103; HF N104.....
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, 2025.03.24

Place, date

Guoping Wang

General manager

Tel.: +49 (0) 211 2398900
Fax: +49 (0) 211 23989099
E-Mail: info@caretechion.de

European authorized representative Declaration

Caretechion GmbH
Niederrheinstr. 71,
40474 Düsseldorf, Germany
as the **EU Authorized Representative** for

Manufacturer:
Anji Hengfeng Sanitary Material Co., Ltd
No.218, Liuguanli Road, Dipu Sub-district, Anji County,
313300 Zhejiang, P.R. China

Caretechion GmbH will assume the duties of a European authorized representative and fulfill our obligation to monitor the entrance of this product into the EU market.

Registration number	Legal basis	Class	Product name
DE/CA20/00185876	Verordnung (EU) 2017/745 (MDR)	I	Tourniquet
DE/CA20/00183383	Verordnung (EU) 2017/745 (MDR)	I	Emergency blanket
DE/CA20/00182896	Verordnung (EU) 2017/745 (MDR)	I	Lap Sponge
DE/CA20/00182258	Verordnung (EU) 2017/745 (MDR)	I	Wound Dressing
DE/CA20/00182067	Verordnung (EU) 2017/745 (MDR)	I	Non-woven Caps
DE/CA20/00181991	Verordnung (EU) 2017/745 (MDR)	I	Gauze Swab
DE/CA20/00181613	Verordnung (EU) 2017/745 (MDR)	I	Shoe Covers
DE/CA20/00181612	Verordnung (EU) 2017/745 (MDR)	I	Gauze Roll
DE/CA20/00181330	Verordnung (EU) 2017/745 (MDR)	I	Isolation Gown
DE/CA20/00179749	Verordnung (EU) 2017/745 (MDR)	I	First Aid Bandage
DE/CA20/00188318	Verordnung (EU) 2017/745 (MDR)	I	Disposable underpad
DE/CA20/00188192	Verordnung (EU) 2017/745 (MDR)	I	Non woven dressing
DE/CA20/00187503	Verordnung (EU) 2017/745 (MDR)	I	Compressed Gauze
DE/CA20/00187403	Verordnung (EU) 2017/745 (MDR)	I	Mouth to mouth breathing mask
DE/CA20/00187331	Verordnung (EU) 2017/745 (MDR)	I	Gloves
DE/CA20/00186390	Verordnung (EU) 2017/745 (MDR)	I	Scissors
DE/CA20/00186058	Verordnung (EU) 2017/745 (MDR)	I	First Aid Kit
DE/CA20/00185984	Verordnung (EU) 2017/745 (MDR)	I	Cotton wool roll
DE/CA20/00180171	Verordnung (EU) 2017/745 (MDR)	I	Face Shield
DE/CA20/00179415	Verordnung (EU) 2017/745 (MDR)	I	Adhesive Plaster
DE/CA20/00178541	Verordnung (EU) 2017/745 (MDR)	I	Bandage
DE/CA20/00177681	Verordnung (EU) 2017/745 (MDR)	I	Medical Disposable Face Mask

DE/CA20/00193410	Verordnung (EU) 2017/745 (MDR)	Is	Sterile First Aid Bandage
DE/CA20/00193411	Verordnung (EU) 2017/745 (MDR)	Is	Sterile Bandage

Under Verordnung 11 of the EU Medical Device Regulation (EU) 2017/745 (MDR), an EU REP must be explicitly designated as a "EU Authorised Representative" (as defined in Article 2(32) MDR), Manufacturer, Anji Hengfeng Sanitary Material Co., Ltd., must beresponsible for the quality of the products the legal distribution of the products, and any other problemscaused by the quality of the products.

The manufacturer, Anji Hengfeng Sanitary Material Co., Ltd., has the obligation to comply with the requirements of the EU Authorized Representative, Caretechion GmbH, and to comply with relevant EU regulations before exporting to the EU and engaging in any sales behaviors in the EU. This manufacturer's relevant importers also have the obligation to provide Caretechion GmbH with sales lists in a timely manner. The remaining terms and agreements are in accordance with the European Authorized Representative Agreement (NO. EU200368).

Medical devices that are brought to market are required to possess a device identification system (UDI) in accordance with the MDR. Additionally, manufacturers, authorized representatives, and importers must register themselves with the European database for European medical devices (Eudamed). The necessary information to be provided at the time of registration can be found in Annex VI of the MDR.

Currently, Eudamed is not yet operational. Thus, it is sufficient for manufacturer to have notified the products in accordance with current laws and regulations pertaining to the aforementioned requirement.
Upon full implementation of Eudamed, it is expected that manufacturers or their authorized representatives will register the above-mentioned medical devices within eighteen months.

It is also important to note that the registration of the notification pertaining to the delivery of said products is a mere administrative procedure. This receipt confirmation does not constitute a decision regarding the classification of the relevant products as medical devices within the meaning of Article 1 of the Medical Devices Act, nor does it pertain to their classification into risk class I.

Caution: This declaration will automatically become invalid if the medical device is written off or removed from the EU market by the local competent authority, or if the EU Authorized Representative Agreement with Caretechion GmbH is terminated.

Caretechion GmbH
Niederrheinstr. 71, 40474 Düsseldorf
Tel.:0211 239 890 0 Fax:0211 239 890 99
E-Mail:info@caretechion.de
Amtsgericht Düsseldorf HRB 82833
Ust -ID :DE319481632

EU REP: CaretechionGmbH
Jian Wang

General manager
Manufacturer: Anji Hengfeng Sanitary Material Co., Ltd
Guoping Wang

Date 2025.03.24 Place Düsseldorf