

EU Certificate

Production Quality Assurance REGULATION (EU) 2017/745 on Medical Devices Annex XI Part A

Registration No.: DZ 2111271-1

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

EUDAMED Single Registration No.: CN-MF-000013051

Products: Products of class I, sterile:
M030302 - PROTECTION SYSTEMS
-Sterile First Aid Bandages
M030401 - ELASTIC COMPRESSION BANDAGES
-Sterile Bandages
The scope of certification is limited to the aspects relating to
establishing, securing and maintaining sterile conditions

Authorized representative(s): Caretechion GmbH
Niederrheinstr.71,40474 Duesseldorf,Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-09
1	Address change	2025-03-24

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation.

If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 326065257-200

Effective date: 2025-03-24

Expiry date: 2028-05-08

Issue date: 2025-03-24



Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
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This certificate can be validated on <https://www.certipedia.com>

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