

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.**
Ancheng, Dipu Town, 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 Bandage
M030401 - ELASTIC COMPRESSION BANDAGES
-Sterile Bandage

The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions

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

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-05-09

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.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.