

Declaration of Conformity

1. Manufacturer: Zhende Medical Co.,Ltd.
Gaobu Town, 312035, Shaoxing, Zhejiang, China
2. EC Representative: Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80 20537 Hamburg Germany
3. Product name Foam Dressing
UMDNS Code: 11323

Classification (MDD, Annex IX): IIb, rule 4

Conformity Assessment Route: Annex II section 3

We herein declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard Applied:

EN ISO 15223-1:2021 EN ISO 13485:2016 EN ISO 14971:2019

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339
München, Germany

NB Identification number: 0123

(EC) Certificate(s): G1 095972 0003 Rev.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2016-07-27

Place, Date of Issue: Shaoxing, 2016-07-27

Confirmation Letter: CL 095972 0017 Rev. 00

Issue Date: 2024-05-29 Expiry Date: 2028-12-31

Signature:



Date:2025-07-11

Name: Chen Ming

Position: Regulatory Director

REF	Product Description
MAB7030SA	clevefoam 13 x 9,5 cm foam dressing heel
MAB7031SA	clevefoam 10 x 10 cm foam dressing
MAB7032SA	clevefoam 15 x 15 cm foam dressing
MAB7033SA	clevefoam 20 x 20 cm foam dressing
MAB7034SA	clevefoam tracheo 10 x 9 cm foam dressing trecheostomy
MAB7035SA	clevefoam border 15 x 15 cm foam dressing with border
MAB7036SA	clevefoam border 20 x 20 cm foam dressing with border
MAB7037SA	clevefoam border heel 25 x 23,5 cm foam dressing with border heel
MAB7038SA	clevefoam border sacrum 23 x 23 cm foam dressing with border sacrum
MAB7039SA	clevefoam border 10 x 10cm foam dressing with border
MAB7040SA	clevefoam border 7,5 x 7,5cm foam dressing with border