



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 Super Absorbent Dressing
GMDN Code: 46854

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

Conformity Assessment Route: Annex II section 3

We hereby 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, 2019-08-05

Confirmation Letter: CL 095972 0017 Rev. 00

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

Signature:

A handwritten signature in black ink, appearing to be 'Chen Ming'.

Date: 2025-07-11

Name: Chen Ming

Position: Regulatory Director



REF	Product Description
MAB1031SA	clevesorb 10 x 10 cm super absorbent dressing
MAB1032SA	clevesorb 10 x 20 cm super absorbent dressing
MAB1033SA	clevesorb 15 x 20 cm super absorbent dressing
MAB1034SA	clevesorb 20 x 20 cm super absorbent dressing
MAB1035SA	clevesorb 20 x 30 cm super absorbent dressing