

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 Silicone Foam Dressing
GMDNS Code: 46854
Classification (MDD, Annex IX): IIb, rule 4
Conformity Assessment Route: Annex II excluding (4)

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 15233-1:2021

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

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
MAB8031SA	clevesil 10 x 10cm silicone foam dressing
MAB8032SA	clevesil 12,5 x 12,5cm silicone foam dressing
MAB8033SA	clevesil 15 x 15cm silicone foam dressing
MAB8034SA	clevesil heel 20 x 13cm silicone foam dressing heel
MAB8035SA	clevesil border 10 x 10cm silicone foam dressing with border
MAB8036SA	clevesil border 12,5 x 12,5cm silicone foam dressing with border
MAB8037SA	clevesil border 15 x 15cm silicone foam dressing with border
MAB8038SA	clevesil border 20 x 20cm silicone foam dressing with border
MAB8039SA	clevesil border sacrum 18 x 18cm silicone foam dressing with border sacrum
MAB8040SA	clevesil border sacrum 23 x 23cm silicone foam dressing with border sacrum
MAB8041SA	clevesil border heel 25 x 23,5cm silicone foam dressing with border heel
MAB8042SA	clevesil border 7,5 x 7,5cm silicone foam dressing with border
MAB18031SA	cleveflex plus 10 x 10cm POST OP silicon dressing
MAB18032SA	cleveflex plus 6 x 7cm POST OP silicon dressing
MAB18033SA	cleveflex plus 10 x 20cm POST OP silicon dressing
MAB18034SA	cleveflex plus 10 x 25cm POST OP silicon dressing
MAB18035SA	cleveflex plus 10 x 30cm POST OP silicon dressing
MAB18036SA	cleveflex plus 10 x 35cm POST OP silicon dressing