

EU Declaration of Conformity

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

Add.: North Shangxia Rd., Dongjiang Hi-tech Industry Park, 516005, HuiZhou, P. R. China.

SRN: CN-MF-000007344

Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Add.: Eiffestrasse 80, 20537 Hamburg, Germany

SRN of Authorised Representative: DE-AR-000000001

Product Name: Alginate Dressing

Trade Name: Cutimed®

Type/Specification: See Annex I

Intended purpose: Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including: surface trauma, cavity wounds, pressure ulcers, diabetic foot ulcers, venous/arterial leg ulcers, donor sites, post-operative wounds.

Basic UDI-DI: Sheet: 69406101AD0005YT

EMDN Code: M040402 ALGINATE DRESSINGS

GMDN Code: 43186

Classification: II b, REGULATION (EU) 2017/ 745(MDR) Annex VIII, rule 4

Conformity Assessment: REGULATION (EU) 2017/745, Annex IX Chapter I +III

General Applicable Regulations: REGULATION (EU) 2017/745 (MDR), Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Standards Applied: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, CEN ISO/TR 24971:2020, EN ISO 4180:2019, ASTM D4169:2022, ASTM D4577:2019, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2015, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, ISO 10993-10:2021, EN ISO 10993-11: 2018, EN ISO 10993-12:2021, EN ISO 10993-17:2009, EN ISO 10993-18:2020, EN ISO 11137-1:2015, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2:2015, EN ISO 11137-3:2017, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 15223-1:2021, EN ISO 20417:2021, ASTM F 1980:2021, EN ISO 14155:2020, MEDDEV. 2.7.1 Rev.4, MEDDEV. 2.12-2 Rev.2, MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG 2020-8, MDCG 2020-13, MEDDEV 2.12/1 rev 8, EN 13726-1:2002, EN 13726-1:2002/AC:2003, EN ISO 1798:2008, EN 62366-1:2015, EN ISO 10993-23:2021.

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

Identification Number: 

(EC)Certificate(s): G10 065520 0040 Rev.01

Expire Date of the Certificate: 2027-09-04

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

The manufacturer is exclusively responsible for the declaration of conformity.

Signature:

Place and Date of Issue:

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 Huizhou 2024-09-29

Yang Zhang

Person Responsible for Regulatory Compliance

Annex I

This appendix declares the products included in the above referenced Declaration of Conformity.

Items	BSN's Article Number	Sizes
Cutimed® Alginate Dressing	72634-00012-00 CMED ALG STE 5X5CM W 10 INT. 55	50X50mm
	72634-00013-00 CMED ALG STE 10X10CM W 10 INT. 55	100X100mm
	72634-00014-00 CMED ALG STE 10X20CM W 10 INT. 55	100X200mm
	72634-00015-00 CMED ALG STE 2.5X30CM FLAT ROPE W 5 INT. 55	25X300mm