


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
Product Name: Alginate Dressing
Trade Name: Cutimed®
Type/Specification: See Annex I
Basic UDI-DI: /
EMDN Code: M040402
GMDN Code: 43186
Classification: IIb, MDD 93/42/EEC Appendix IX, Rule4
Conformity Assessment: Annex II.3 of MDD 93/42/EEC
General Applicable Regulations: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC);
Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Article 120.
Standards Applied: All applicable standards
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München, Germany
Identification Number: 
(EC)Certificate(s): G1 065520 0034 Rev. 02
Expire Date of the Certificate: 2028-12-31

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:

Huizhou / 2023.8.11

Yang Zhang

Person Responsible for Regulatory Compliance

Annex I

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

Items	BSN article number	Sizes
Cutimed® Alginate Dressing	72634-00008-01	50mm×50 mm
	72634-00009-01	100mm×100 mm
	72634-00010-01	100mm×200 mm
	72634-00011-01	25mm×300 mm