

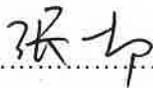
EU Declaration of Conformity

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.: Eifflstrasse 80, 20537 Hamburg, Germany
Product Name: Alginate Dressing
Trade Name: LUOFUCON®
Type/Specification: See Annex I
Basic UDI-DI: /
EMDN Code: M040402
GMDN Code: 43186
Classification: IIb, MDD 93/42/EEC Appendix IX, Rule 4
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.

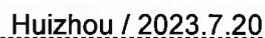
Signature:



Yang Zhang

Person Responsible for Regulatory Compliance

Place and Date of Issue:



Annex I

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

Alginate Dressing (Sheet)

Size	Length, mm	Width, mm
50×50mm	50	50
100×100mm	100	100
200×200mm	200	200
300×20mm	300	20

Special size product can be ordered by customer. But the area or the weight of largest size can not exceed 400cm² and 8gram.

Alginate Dressing (Adhesive)

Size	Adhesive		Alginate	
	Length, mm	Width, mm	Length, mm	Width, mm
50×50mm	50	50	20	20
100×60mm	100	60	60	30
100×100mm	100	100	50	50
200×200mm	200	200	150	150

Special size product can be ordered by customer. But the area or the weight of largest size can not exceed 400cm² and 8gram.

Alginate Dressing (Rope)

Size	Length, mm	Weight, g
305mm(2g)	305	2