

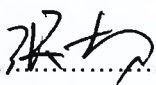
EU Declaration of Conformity

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: Silicone Wound Contact Dressing
Trade Name: LUOFUCON®
Type/Specification: See Annex I
Basic UDI-DI: /
EMDN Code: M040407
GMDN Code: 46855
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.

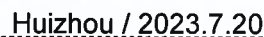
Signature:



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.

Items (Type D & Type DW & Type DW-P)	Size Border size range: L: 80-330 mm; W: 50-200 mm Product size range: L: 70-320 mm; W: 50-200 mm			
	Border Size		Product Size	
	Length (mm)	Wide (mm)	Length (mm)	Wide (mm)
70×50	80±2	50±2	70±2	50±2
100×75	110±3	80±2	100±2	75±2
160×80	170±3	80±2	160±3	80±2
100×100	110±3	100±2	100±2	100±2
150×100	160±3	100±2	150±3	100±2
150×120	160±3	120±3	150±3	120±3
175×100	185±3	100±2	175±3	100±2
150×150	160±3	150±3	150±3	150±3
320×200	330±3	200±3	320±3	200±3
Items (Type S & Type S-P)	Size Size range: L: 70-320 mm; W: 50-200 mm			
	Length (mm)		Wide (mm)	
70×50	70±2		50±2	
100×75	100±2		75±2	
160×80	160±3		80±2	
100×100	100±2		100±2	
150×100	150±3		100±2	
150×120	150±3		120±3	
175×100	175±3		100±2	
150×150	150±3		150±3	
320×200	320±3		200±3	