


## 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 Postoperative Dressing  
**Trade Name:** LUOFUCON®  
**Type/Specification:** See Annex I  
**Basic UDI-DI:** /  
**EMDN Code:** M040101  
**GMDN Code:** 46854  
**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:**

  
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**Yang Zhang**

**Person Responsible for Regulatory Compliance**

**Place and Date of Issue:**

..... Huizhou / 2023.7.20 .....

## Annex I

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

The range of sizes	The representative sizes	REF Code
Dressing: Length: 80~500mm Width: 60~200mm Core: Length: 50~430mm Width: 30~145mm Border: 10~40mm	80×60(50×30)mm	OP080060A
	90×60(45×30)mm	OP090060A
	100×90(60×45)mm	OP100090A
	100×100(60×60)mm	OP100100A
	150×90(100×45)mm	OP150090A
	150×100(100×60)mm	OP150100A
	150×150(100×100)mm	OP150150A
	150×145(100×95)mm(Sacrum)	OP150145AS
	175×150(125×100)mm	OP175150A
	175×170(125×120)mm(Sacrum)	OP175170AS
	200×100(145×45)mm	OP200100A
	250×100(190×45)mm	OP250100A
	300×100(240×45)mm	OP300100A
	350×100(290×45)mm	OP350100A
	250×200(190×145)mm	OP250200A
	500×200(430×145)mm	OP500200A