

# EU Declaration of Conformity

## According to ANNEX IV of the Medical Device Regulation (EU) 2017/745

Manufacturer: Zhejiang Longterm Medical Technology Co., Ltd.  
ShuangShan Road 277, Fuxi Street, Deqing County, Huzhou City, Zhejiang Province, People's Republic of China.

SRN of the Manufacturer: SRN: CN-MF-000001161

Authorised Representative: Lotus NL B.V.  
Koningin Julianaplein 10, 1e Verd, 2595AA The Hague, The NETHERLANDS

SRN of the Authorised Rep.: NL-AR-000000121

Product Name: Hydrocolloid dressing

Product Code: See attachment

Basic UDI-DI of Product: 69263655200017Q

Intended Purpose: The device can be used in the management of low to moderate exuding wounds like venous leg ulcers, pressure ulcers, donor sites, postoperative wounds, skin abrasions and small wounds.

EMDN Code: M040403

Classification (MDR, Annex VIII): **IIb, rule 4**

Conformity Assessment Procedure: **Annex IX ( chapter I/III+Sec 4)**

We (manufacturer) herewith state that the above-mentioned product is in conformity with the following Medical Device Regulation, Common Specifications and Product Standards. We are solely responsible for the EU declaration of conformity.

The applicable Medical Device Regulation, Common Specifications and Product Standards:

Medical Device Regulation (EU) 2017/745

Common Specifications: NA

Standards:

ISO10993-1, EN ISO10993-5, EN ISO10993-7, ISO10993-10, EN ISO10993-12, EN ISO11737-1, EN ISO11737-2, ISO11737-3, ISO 14971, EN ISO11607-1, EN ISO11607-2, EN ISO15223-1, ISO15223-2, EN ISO 11137-1, ISO11137-2, ISO11138-1, ISO11138-2, BS EN 17141, ISO 14644-1, ISO 14644-2, ISO 29862, YY0148, EN 13726-1, EN13726-3, ASTM F 1980, ISO20417, EN556-1, ISO2859-1, EN ISO 13485, EN 62366-1, Chinese pharmacopoeia

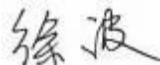
Notified Body: TÜV SÜD Product Service GmbH  
Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123

(EC) Certificate(s): G10 083478 0030 Rev.00

Expire date of the Certificate: 2028-04-10

Signature:



Name: Mr. Bo Xu

Position: Management Representative

Place, Date of Issue: Deqing, 2023-04-11

## Annex Product code list

| Item  | Specification | Item       | Specification |
|---|---------------|------------|---------------|
| PU film                                     |               |            |               |
| With thin border                            |               | Extra thin |               |
| G1302                                       | 5cm*5cm       | G1402      | 5cm*5cm       |
| G1305                                       | 7.5cm*7.5cm   | G1405      | 7.5cm*7.5cm   |
| G1307                                       | 8cm*12cm      | G1408      | 10cm*10cm     |
| G1308                                       | 10cm*10cm     | G1409      | 10cm*20cm     |
| G1309                                       | 10cm*20cm     | G1415      | 15cm*15cm     |
| G1314                                       | 15cm*18cm     | G1417      | 15cm*20cm     |
| G1315                                       | 15cm*15cm     | G1418      | 20cm*20cm     |
| G1316                                       | 15cm*18cm     | G1419      | 20cm*30cm     |
| G1317                                       | 15cm*20cm     | G1422      | 25cm*25cm     |
| G1318                                       | 20cm*20cm     | G1430      | 5cm*10cm      |
|   |               | G1431      | 5cm*15cm      |
|   |               | G1432      | 5cm*20cm      |
| PU foam                                     |               |            |               |
| With thin border                            |               | Extra thin |               |
| G1502                                       | 5cm*5cm       | G1602      | 5cm*5cm       |
| G1504                                       | 7cm*7cm       | G1605      | 7.5cm*7.5cm   |
| G1505                                       | 7.5cm*7.5cm   | G1608      | 10cm*10cm     |
| G1508                                       | 10cm*10cm     | G1615      | 15cm*15cm     |
| G1514                                       | 14cm*14cm     | G1617      | 15cm*20cm     |
| G1515                                       | 15cm*15cm     | G1618      | 20cm*20cm     |
| G1516                                       | 15cm*18cm     | G1700      | 2.1cm*6.1cm   |
| G1517                                       | 15cm*20cm     | G1701      | 2.6cm*7.8cm   |
| G1518                                       | 20cm*20cm     | G1702      | 2.7cm*8.5cm   |
|   |               | G1703      | 3.2cm*9cm     |
|   |               | G1704      | 3.9cm*9.1cm   |
| Different shapes (PU film with thin border) |               |            |               |
| 5045  | 28mm*46mm     | 5058       | 21mm*65mm     |
| 5046  | 37mm*55mm     | 5059       | 36mm*62mm     |
| 5047  | 44mm*69mm     | 5060       | 40mm*42mm     |
| 5048  | 28mm*46mm     | 5061       | 16mm*60mm     |
| 5049  | 37mm*55mm     | 5062       | 47mm*68mm     |
| 5050  | 44mm*69mm     | 5063       | 85mm*140mm    |
| 5051  | 37mm*55mm     | 5064       | 41mm*62mm     |
| 5052  | 44mm*69mm     | 5065       | 18mm*50mm     |
| 5053  | 15mm*50mm     | 5066       | 22mm*41mm     |
| 5054  | 25mm*60mm     | 5067       | 29mm*60mm     |
| 5055  | 18mm*61mm     | 5068       | 17mm*48mm     |
| 5056  | 20mm*45mm     | 5079       | 15mm*50mm     |
| 5057  | 23mm*47mm     | 5080       | 20mm*60mm     |
| 5108  | Φ8mm          | 5081       | 28mm*69mm     |
| 5102  | Φ10mm         | 5082       | 28mm*69mm     |
| 5103  | Φ12mm         | 5083       | 25mm*65mm     |
| 5104  | Φ15mm         |            |               |