

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: Absorbent dressing

Product Code: See attachment

Basic UDI-DI of Product: 692636552000886

Intended Purpose: Absorbent dressing may be applied to moderately to heavily
exuding wounds like partial thickness burns, donor sites, leg ulcers,
pressure ulcers, etc.

EMDN Code: M040204

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 ISO11135, ISO/TS11135-2, ISO11138-1, ISO11138-2, BS EN 17141, ISO 14644-1, ISO 14644-2, ISO 29862, EN 13726-1, 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

Specification:

Item	Specification	Item	Specification
Non-adhesive		coated with silicone	
S00404	10 cm * 10cm	S10203	6 cm * 7cm
S00406	10cm * 15cm	S10304	7cm * 10cm
S00408	10 cm * 20 cm	S10404	10 cm *10cm
S00410	10 cm * 25 cm	S10406	10cm * 15cm
S00412	10 cm* 30cm	S10408	10 cm * 20 cm
S00507	12 cm *18cm	S10410	10 cm * 25 cm
S00606	15 cm * 15cm	S10412	10 cm* 30cm
S00608	15 cm * 20cm	S10606	15 cm * 15cm
S00609	16 cm * 22cm	S10608	15 cm * 20cm
S00808	20 cm * 20cm	S10808	20 cm * 20cm
S00810	20 cm * 25cm	S10810	20 cm * 25cm
S01212	30 cm * 30cm	S10812	20 cm * 30cm
S00812	20 cm * 30cm	S11010	25 cm * 25cm
S01010	25 cm * 25cm	S11212	30 cm * 30cm
S01510	40cm*25cm	S10710	17.5cm*27.5cm
S00505	12.5cm*12.5cm	S10610	15cm*25cm
S00509	12.5cm*22.5cm	SS01010	10 cm * 10cm
		SS00909	9cm * 9cm
		SS01313	13cm * 13cm
		SS01717	17cm * 17cm
		SS01519	15cm * 19cm
		SS01515	15cm * 15cm