

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: Silicone foam dressing

Product Code: See attachment

Basic UDI-DI of Product: General: 69263655200047W Extra-thin: 69263655200137X

Intended Purpose: The non-combined extra-thin device is designed for a wide range of non
to moderate exuding wounds, such as leg and foot ulcers, pressure
ulcer, partial thickness burns, radiation skin reactions. It can also be
used as protection of compromised and/or fragile skin.

EMDN Code: The non-combined regular device is indicated for the management of a
wide range of exuding wounds such as leg and foot ulcers, pressure
ulcers, traumatic wounds, such as skin tears and secondary healing
wounds.
M040407

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:

ISO10993-18, 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, YY0148, EN 13726-1, EN 13726-2, 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
Without border		With border	
S71022	5 cm *5cm	S72070heel and elbow	12.5cm*20cm
S71033	7.5 cm *7.5cm	S72033	7.5 cm *7.5cm
S71044	10 cm *10cm	S72044	10 cm *10cm
S71055	12.5 cm *12.5cm	S72046	10 cm *25cm
S71066	15 cm *15 cm	S72055	12.5 cm *12.5cm
S71068	15 cm *20 cm	S72066	15 cm *15 cm
S71144	10 cm *10cm	S72068	15 cm *20 cm
S71166	15 cm *15 cm	S72070	15 cm *18 cm
S71047	10 cm *17.5cm	S72072	22.5cm X 22.5cm
S71067	15 cm *18 cm	S72073	10cm x 30cm
S71058	14 cm *21 cm	S72073-1	10cm*15cm
S71077	10 cm *20 cm	S72074	18 cm *20 cm
S71088	20 cm *20 cm	S72075	18.5cm*24cm
S71058-R	14cm X 21cm	S72076	30cm*25.5cm
S71058-L	14cm X 21cm	S72077	10cm x 20cm
S71034	3cm X 4cm	S72077-1	18 cm *18 cm
S71073	7cm X 11cm	S72078	20cm x 20cm
S71047	10cm X 17.5cm	S72079	20cm*20.8cm
S71067	15cm X 18cm	S72080	26.5cm*20cm
S71082	10cm X 25cm	S72081	15cm*18cm
S71083	10cm X 30cm	S72082	10cm x 25cm
		S72088	23 cm *23 cm
With border		S72099	20 cm *30 cm
S80002-1	9cm X 10cm	S80001	6cm X 8cm
S80003-1	10cm X 20cm	S80002	10cm X 11cm
S80004-1	10cm X 25cm	S80003	11cm X 20cm
S80005-1	10cm X 30cm	S80004	11cm X 25cm
S80006-1	10cm X 35cm	S80005	11cm X 30cm
		S80006	11cm X 36cm
		S80007	9cm X 15cm
		S80008	10cm X 10cm
Extra thin			
Without border		With border	
S74033	6 cm *8.5cm	S73022	4 cm *5cm
S74044	10cm *10cm	S73033	5cm *12.5cm
S74055	15 cm *15cm	S73044	7.5 cm *7.5cm
S74068	20cm *50 cm	S73055	10 cm *10cm
S74034	3cm X 4cm	S73066	15 cm *15 cm
		S73071	18.5 cm *24cm
		S73022-1	5cm X 5cm