

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: SOL-M IV Dressing

Product Code: See attachment

Basic UDI-DI of Product: 69263655100037H

Intended Purpose: Sterile wound dressing are applied for all kinds of wounds
protection or external fixation (like I.V. sites)

EMDN Code: M040101

Classification (MDR, Annex VIII): **Is, rule 4**
Conformity Assessment Procedure: **Annex XI Part A**

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 ISO11737-1, EN ISO11737-2, ISO 14971, EN ISO11607-1, EN ISO11607-2, EN ISO15223-1, ISO15223-2, EN ISO11135, ISO/TS11135-2, ISO11138-1, ISO11138-2, ISO 14644-1, ISO 14644-2, ISO 29862, ISO 29863, EN 13726-1, ASTM F 1980, ISO20417, EN556-1 · ISO2859-1, EN ISO 13485, Chinese pharmacopoeia
Latest Version

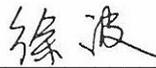
Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123

(EC) Certificate(s): G21 083478 0029 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

Attachment:

Ref No.	Product Name	Product Description
DRE001	SOL-M IV Dressing	SOL-M IV Dressing Non-woven 6cm*8cm
DRE002	SOL-M IV Dressing	SOL-M IV Dressing PU Film Pre-Cut, 7cm*9cm
DRE003	SOL-M IV Dressing	SOL-M IV Dressing PU Film,6cm*7cm