

# 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

Device Group: Fixing Dressing

Product Name: Medical Tapes

Trade Name: Skin Care roll

Product Code: PU tape (roll): 5cm\*1m, 5cm\*5m, 5cm\*9.1m, 5cm\*10m, 10cm\*1m  
10cm\*5m, 10cm\*9.1m, 10cm\*10m, 15cm\*1m, 15cm\*5m,  
15cm\*9.1m, 15cm\*10m

Basic UDI-DI of Product: 692636550000274

Intended Purpose: Product is applicable to a variety of in-dwelling catheters,  
electrodes, dressings, bandages or other external fixation.

EMDN Code: M040102

Classification (MDR, Annex VIII): **I, rule 1**

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, ISO 14971, EN ISO11607-1, EN ISO11607-2,EN ISO15223-1,  
ISO15223-2, ISO 29862, ISO 29863,ASTM F 1980, ISO20417, EN556-1, ISO2859-1, EN ISO 13485,  
Chinese pharmacopoeia  
Latest Version

(EC) Certificate(s): Q5 083478 0025 Rev.02

Expire date of the Certificate: 2025-03-31

Signature: 

Name: Mr. Bo Xu

Position: Management Representative

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