







## **Certificate**

No. Q5 083478 0025 Rev. 05

**Holder of Certificate: Zhejiang Longterm** 

Medical Technology Co., Ltd.

ShuangShan Road 277, Fuxi Street, Deqing County 313200 Huzhou City, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 



**Design and Development, Production and Distribution Scope of Certificate:** 

of medical device

(For detailed information see following page).

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 083478 0025 Rev. 05

Report No.: SH2578201 CN1

Valid from: 2025-04-01 Valid until: 2028-03-31

2025-02-10

Christoph Dicks

Head of Certification/Notified Body

Date.







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No. Q5 083478 0025 Rev. 05

ISO 13485:2016 Applied Standard(s):

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Zhejiang Longterm Medical Technology Co., Ltd.

ShuangShan Road 277, Fuxi Street, Deqing County, 313200 Huzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF

CHINA

Design and Development, Production and Distribution of Sterile medical devices including Hydrocolloid dressing, Alginate dressing, Foam dressing, Silicone foam dressing, Hydrogel dressing, Absorbent dressing, Negative pressure wound therapy dressing, Silicone net, Negative pressure wound therapy silicone foam dressing, Gelling fibre dressing, Silicone dressing ultimate.

Production and Distribution of Sterile medical devices including Sterile wound dressing, Skin closure strips, Surgical drapes, Fecal collection bags, Sterile wound plasters, Scar reducing emollient, Ostomy bags and attachments, Infusion plasters, Urinary drainage bag/collection bag, Medical silicone tapes, Medical tapes, Hydrocolloid patch for wound, Equipment cover used in operation room, Sterile hydrocolloid dressing, Catheter fixing dressing, Hydrogel eye pad, Urostomy bag, Urinary collection bag, Compression hemostatic dressing, Wound drainable bag, Medical protective clothing, Surgical mask.

Production and Distribution of Non-sterile medical devices including Skin closure strips, Surgical drapes, Fecal collection bags, Scar reducing emollient, Ostomy bags and attachments, Infusion plasters, Urinary drainage bag/collection bag, Medical silicone tapes, Medical tapes, Hydrocolloid patch for wound, Equipment cover used in operation room, Catheter fixing dressing, Hydrogel eye pad, Urostomy bag, Urinary collection bag, Compression hemostatic dressing, Wound drainable bag, Medical protective clothing, Surgical mask.



