ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 083478 0030 Rev. 00

Manufacturer:

Zhejiang Longterm Medical Technology Co., Ltd.
ShuangShan Road 277, Fuxi Street, Deqing County
313200 Huzhou City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000001161

Authorized Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA The Hague, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 083478 0030 Rev. 00

Report No.: SH22782MDR01

Valid from: 2023-04-11
Valid until: 2028-04-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-04-11

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIb
Device Group:	M040204 - NON-ADHERENT ABSORBENT DRESSINGS
Intended Purpose:	Absorbent dressing may be applied to moderately to heavily exuding wounds like partial thickness burns, donor sites, leg ulcers, pressure ulcers, etc.

Classification:	Class IIb
Device Group:	M040402 - ALGINATE DRESSINGS
Intended Purpose:	The device may be applied to moderate to heavy exuded wounds like donors sites, leg ulcers, pressure ulcers ,cavity wounds and most other granulating wounds.

Classification:	Class IIb
Device Group:	M040403 - HYDROCOLLOID DRESSINGS
Intended Purpose:	The device can be used in the management of low to moderate exuding wounds like venous leg ulcers, pressure ulcers, donor sites, postoperative wounds, skin abrasions and small wounds.

Classification:	Class IIb
Device Group:	M040406 - POLYURETHANE DRESSINGS
Intended Purpose:	The non-combined device The non-combined device may be applied to a variety of exuding wounds, including leg and decubitus ulcers, sutured wounds, donor sites, and fungating wounds. It is particularly useful for dressing wounds such as sacral pressure sores due to its pressure-reducing effect The device combined with other substances The device combined with other substances can be used to treat full- and partial thickness acute and chronic wounds, including pressure, diabetic foot and venous leg ulcers, traumatic, postoperative and dehisced surgical wounds, skin flaps and grafts, explored fistulae and partial-thickness burns. Large cavity wounds with high exudate levels are particularly suited to NPWT, although it can also be used on wounds with mild or moderate levels of exudates.

Classification:	Class IIb
Device Group:	M040407 - SILICONE DRESSINGS
Intended Purpose:	The device combined with other substances The device combined with other substances is intended to be used along with negative pump for the patients who may benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

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The non-combined extra-thin device
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.

The non-combined regular device
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.

The non-combined net device
The non-combined net device is a versatile wound contact dressing that can be used on many exuding wounds when used with an outer absorbent dressing. Typical exuding wounds are: Painful wounds Skin tears Skin abrasions, blistering, lacerations, and traumatic wounds,Surgical wounds,Partial thickness burns, Partial and full thickness grafts, Radiated skin, Leg and foot ulcers.It can also be used as protective layer on non-exuding wounds and on areas with fragile skin.

The validity of this certificate depends on conditions and/or is limited to the following: - none -

Revision History:

Rev.	Dated	Report	Description
00	2023-04-11	SH22782MDR01	Initial issuance

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