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 065520 0040 Rev. 01

Manufacturer:

Huizhou Foryou Medical Devices Co., Ltd.
North Shangxia Rd.
Dongjiang Hi-tech Industry Park
516005 HuiZhou
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000007344

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

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, 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:G10 065520 0040 Rev. 01

Report No.:	SH2238503
Preceding Certificate No.:	G10 065520 0040 Rev. 00
Valid from:	2024-08-13
Valid until:	2027-09-04
Date of Initial Issuance:	2022-09-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-08-13

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

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

TÜV SÜD
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 065520 0040 Rev. 01

Classification:	Class IIb
Device Group:	M040406 - POLYURETHANE DRESSINGS
Intended Purpose:	Silicone Foam Dressing Border is designed for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds, surgical wounds and skin tears. The dressing may also be used as part of a prophylactic therapy to help prevent pressure ulcers. Silicone Foam Dressing Border Lite is indicated for a wide range of non to low exuding wounds such as Pressure ulcers, Leg and foot ulcers, surgical wounds, traumatic wounds and skin tears. Silicone Foam Dressing Non-border is indicated for a wide range of exuding wounds such as pressure ulcers, leg and foot ulcers, traumatic wounds, and skin tears. Foam Dressing is indicated for moderately to heavily exuding wounds, such as venous leg ulcers, pressure ulcers, diabetic foot ulcers, donor sites, abrasions, and surgical wounds.
Classification:	Class IIb
Device Group:	M040402 - ALGINATE DRESSINGS
Intended Purpose:	Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including: surface trauma, cavity wounds, pressure ulcers, diabetic foot ulcers, venous/arterial leg ulcers, donor sites, post- operative wounds.
Classification:	Class IIb
Device Group:	M040404 - CELLULOSE AND/OR MODIFIED CELLULOSE DRESSINGS, NON-COMBINED OR COMBINED WITH OTHER SUBSTANCES
Intended Purpose:	Gelling Fiber Dressing is used for the management of moderately to heavily exuding acute or chronic wounds. It can also be pre-moistened for effective use on dry or lightly draining wounds, including： Lower leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers; Surgical wounds (post-operative, donor sites, wounds left to heal by secondary intent, dermatological); Partial thickness burns; Traumatic wounds (abrasions and lacerations); Oncology wounds (if moderately or heavily exuding, superficial or deep).
Classification:	Class IIb
Device Group:	M040407 - SILICONE DRESSINGS
Intended Purpose:	Silicone Wound Contact Dressing is designed for the management of a wide range of exuding wounds such as: skin tears, skin abrasions, surgical incisions, partial thickness burns, lacerations, traumatic wounds, leg and foot ulcers, partial and full thickness

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

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 065520 0040 Rev. 01

grafts, radiation injuries. It can also be used as a protective layer on non-exuding wounds, blisters and on areas with fragile skin.

Classification: Class IIb

Device Group: M040414 - MULTI-LAYER ABSORBENT DRESSINGS

Intended Purpose: Super absorbent dressing is intended for used on moderately to heavily exuding wounds. Such as leg ulcers, pressure ulcers, diabetic foot ulcers and surgical wounds.

Silicone Postoperative Dressing is a self-adhesive absorbent surgical dressing designed for exuding wounds. It is intended for acute wounds, such as surgical wounds, cuts and abrasions.

The validity of this certificate depends on conditions and/or is limited to the following: -n.a-

Revision History:

Rev.	Dated	Report	Description
00	2022-09-05	SH2138501	-
01	2024-08-13	SH2238503	Supplemented: Device(s)/group of device(s) added

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

TÜV®