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. 00

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 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 065520 0040 Rev. 00

Report No.: SH2138501

Valid from: 2022-09-05
Valid until: 2027-09-04

Issue date: 2022-09-05

Christoph Dicks
Head of Certification/Notified Body

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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No. G10 065520 0040 Rev. 00

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

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