FORYOU MEDICAL

EU Declaration of Conformity

Manufacturer:	Huizhou Foryou Medical Devices Co., Ltd.
Add.:	North Shangxia Rd. Dongjiang Hi-tech Industry Park,516005, HuiZhou, P. R. China
SRN:	CN-MF-000007344
Authorised Representative:	Shanghai International Holding Corp. GmbH (Europe)
Add.:	Eiffestraße, 80 20537 Hamburg, Germany
Product Name:	TRACHESEAL Sterile Silicone Foam Dressing
Type/Specification:	See Annex Ⅰ
Basic UDI-DI:	69406101SF00018N
EMDN Code:	M040406 POLYURETHANE DRESSINGS
GMDN Code:	46854
Classification:	IIb，REGULATION (EU) 2017/745（MDR） Appendix VIII, Rule 4
Conformity Assessment:	REGULATION (EU) 2017/745, Annex IX Chapter I+III
General Applicable Regulations:	REGULATION (EU) 2017/745 (MDR)、Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Standards Applied:	EN ISO 13485:2016、EN ISO 14971:2019、ISO 4180:2019、ASTM D 4169-16、ISTA 3A：2018、EN ISO 11607-1:2020 、EN ISO 11607-2:2020、ISO 14644-1:2015、EN ISO 10993-1:2020、EN ISO 10993-3:2014、EN ISO 10993-5:2009 、EN ISO 10993-6:2016、EN ISO 10993-7:2008、EN ISO 10993-7:2008/AC:2009、EN ISO 10993-10:2013、EN ISO 10993-11:2018、EN ISO 10993-12:2021 、EN ISO 11135:2014、EN ISO 11135:2014/A1:2019、EN ISO 11138-1:2017、EN ISO 11138-2:2017、EN ISO 11140-1:2014、EN ISO 15223-1::2021、EN ISO 20417:2021、EN ISO 11737-1:2018、EN ISO 11737-1:2018/A1:2021、EN ISO 11737-2:2020、ASTM F 1980:2016、EN ISO 14155:2011、MEDDEV. 2.7.1 Rev.4、MEDDEV. 2.12-2 Rev.2、MEDDEV 2.12-1 rev 8、EN 13726-1:2002、EN 13726-2:2002、EN 13726-3:2003、EN 13726-4:2003、IEC 62366-1: 2015
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße. 65 • 80339 Munich • Germany
Identification Number:	CE 0123
(EC)Certificate(s):	G10 065520 0040 Rev. 00
Expire Date of the Certificate:	2027-09-04

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

Signature:

.....

Yang Zhang

Person Responsible for Regulatory Compliance

Place and Date of Issue:

Huizhou 2023-03-28

Annex I

This appendix declares the products included in the above referenced Declaration of Conformity.

Code	Sizes
TS0003	7.5cm Oval
TS0004	7.5cm Round
TS0005	7.5cm Square
TS0006	12×10cm

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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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. 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-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Huizhou Foryou Medical Devices Co., Ltd. Article name/no.	Novo Klinik Service GmbH article name/no.	Articel description; intendend purpose	Class
TRACHESEAL TS0003	Novo SealPad TS003	Sterile Silicone Foam Dressing	IIb
TRACHSEAL TS0005	Novo SealPad TS005	Sterile Silicone Foam Dressing	IIb

Dafydd Talbot

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