FORYOU 惠州华阳医疗器械有限公司
Huizhou Foryou Medical Devices Co., Ltd.

惠州市东江高新科技产业园上霞北路1号华阳工业园B区13#厂房
North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, HuiZhou, PEOPLE'S REPUBLIC OF CHINA
电话：0752-5302000
传真：0752-5302020
邮编：516005
网址：www.foryoumedical.com

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Huizhou Foryou Medical Devices Co., Ltd.
Manufacturer address and contact details	North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005 Huizhou, China Tel: +86-752-5302185
Single Registration Number (SRN) (if available)	CN-MF-000007344

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH (Europe)
Authorised Representative address and contact details	Eiffestraße, 80 20537 Hamburg, Germany Telephone number: +49 40 2513175 Email: shholding@hotmail.com
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	TÜV SÜD Product Service GmbH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See attached schedule
End date of extended validity/transition period	31 December 2028

惠州市东江高新科技产业园上霞北路1号华阳工业园B区13#厂房
North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, HuiZhou, PEOPLE'S REPUBLIC OF CHINA
电话：0752-5302000
传真：0752-5302020
邮编：516005
网址：www.foryoumedical.com

We, as the manufacturer declare under our sole responsibility:

- for the listed **Directive Certificate** in the attached schedule, the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificates** as listed in the attached schedule

- Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

  Expires *after* 20 March 2023:

  Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  1) We have obtained the EU Quality Management System Certificate (MDR) for Silicone Foam Dressing on 5 September 2022 pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III(Class IIa and Class IIb Devices).
  2) We have submitted the MDR application to the notified body on 29 July 2022 for the devices listed in the attached schedule and signed written agreement on 12 May 2021(Agreement REF. NO.:065520).

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.
1) We have obtained the EU Quality Management System Certificate (MDR) for Silicone Foam Dressing on 5 September 2022 pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices) .
2) The notified body have conducted QMS On-Site Audit from 20 February 2023 to 22 February 2023 according to EN ISO 13485:2016 and Medical Device Regulation (EU) 2017/745 - Annex IX Chapters I and III for the devices listed in the attached schedule.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

惠州市东江高新科技产业园上霞北路1号华阳工业园B区13#厂房
North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, HuiZhou, PEOPLE'S REPUBLIC OF CHINA
电话：0752-5302000
传真：0752-5302020
邮编：516005
网址：www.foryoumedical.com

Signed for and on behalf of the manufacturer:

Company Name: Huizhou Foryou Medical Devices Co., Ltd.

Location & Date: Huizhou/ 2023-07-20

Signature: 

Print Name: Yang Zhang

Title: Person Responsible for Regulatory Compliance

E-mail address: zhangy@foryougroup.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Medical Hydrogel Dressing, Amorphous Hydrogel Dressing, Foam Dressing, Alginate Dressing, Silicone Foam Dressing, Super Absorbent Dressing, Silicone Wound Contact Dressing, Gelling Fiber Dressing, Silicone Postoperative Dressing	G1 065520 0034 Rev.02	24 July 2023	TÜV SÜD Product Service GmbH with no. 0123	TÜV SÜD Product Service GmbH with no. 0123	31 December 2028	NA
Soluble Hemostatic Gauze	G1 065520 0039 Rev.00	24 July 2023	TÜV SÜD Product Service GmbH with no. 0123	TÜV SÜD Product Service GmbH with no. 0123	31 December 2028	NA
Nasal Dressing, Medical Sponges	G2S 065520 0038 Rev.00	26 May 2024	TÜV SÜD Product Service GmbH with no. 0123	TÜV SÜD Product Service GmbH with no. 0123	31 December 2028	NA