惠州华阳医疗器械有限公司
HUIZHOU FORYOU MEDICAL DEVICES CO., LTD

The Declaration of Conformity

Manufacturer:	**Huizhou Foryou Medical Devices Co., Ltd.**
Add.	**North Shangxia Rd., Dongjiang Hi-tech Industry Park, 516005, HuiZhou, P. R. China.**
European Representative:	**Shanghai International Holding Corp.GmbH(Europe)**
Add.	**Eiffestrasse 80, 20537 Hamburg，Germany**

Products Name:	**Foam Dressing**
Size Specification:	**Listed in Annex Ⅰ**
GMDN Code:	**44970**
Classification:	**Ⅱb，MDD 93/42/EEC Appendix IX, Rule4**
Conformity Assessment Route:	**Annex Ⅱ.3 of MDD 93/42/EEC**

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

The manufacturer is exclusively responsible for the declaration of conformity.

Directives

General Applicable Directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Standards Applied: All applicable standards.

Notified Body:	**TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München，Germany**
Identification Number:	**CE0123**
(EC)Certificate(s):	**G1 065520 0034 Rev. 02**
Expire Date of the Certificate:	**2023-07-24**
Start CE Marking:	**2010-03-18**

Place and Date of Issue: **Huizhou / 2021-05-12**

Signature: _____

Name: **Zhang Yang**

Position: **Management Representative**

Annex I

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

Non-adhesive foam dressing

Item	Foam Pad Size
LUOFUCON® Foam Dressing	5cm × 5cm
	10cm × 10cm
	15cm × 15cm
	20cm × 20cm
LUOFUCON® Foam Dressing with Backing	5cm × 5cm
	10cm × 10cm
	15cm × 15cm
	20cm × 20cm
	13cm × 10cm (Heel)
	10cm × 9cm (Tracheostomy)
LUOFUCON® Foam Dressing with Wound Contact Layer Non-Adhesive	5cm × 5cm
	10cm × 10cm
	15cm × 15cm
	20cm × 20cm
	13cm × 10cm (Heel)
	10cm × 9cm (Tracheostomy)
The Specification of non-adhesive foam dressing can be customized according to the requirements of the customer. The size range is (5~20) cm × (5~20) cm or the area of PU foam is less than 400 cm^2. The Specification of the adhesive foam dressing can be customized according to the requirements of the customer.	

Adhesive foam dressing

Item	Adhesive Border Size	Foam Pad Size
LUOFUCON® Foam Dressing with Border	10cm × 10cm	5cm × 5cm
	15cm × 15cm	10cm × 10cm
	20cm × 10cm	15cm × 5cm
	20cm × 20cm	15cm × 15cm
	22cm × 22cm(Sacrum)	16cm × 15.5cm
LUOFUCON® Foam Dressing with Wound Contact Layer Adhesive	10cm × 10cm	5cm × 5cm
	15cm × 15cm	10cm × 10cm
	20cm × 10cm	15cm × 5cm
	20cm × 20cm	15cm × 15cm
	22cm × 20cm(Sacrum)	16cm × 15.5cm
The Specification of the adhesive foam dressing can be customized according to the requirements of the customer. The size range of border is (5~25) cm × (5~25) cm and the size range of PU foam is (2~20) cm × (2~20) cm. Or the area of border is less than 625cm^2 and the area of PU foam is less than 400cm^2.		

Signature: _____

Name: Zhang Yang

Position: Management Representative

Product Service

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
65520	713296586	+86 21 6142 4449 yu.qiu@tuvsud.com		2023-08-24	1 of 1

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 065520 0043 Rev. 00

Reference: 713296586

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000007344

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

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- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3a) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
24.08.2023

TÜV SÜD Product Service GmbH
Medical and Health Services

2023.08.24

Yu Qiu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Mira Fischer
Application Reviewer

Product Service

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **Silicone Foam Dressing** (Basic UDI -DI: 69406101SF00018N)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 2 **Foam Dressing** (Basic UDI -DI: 69406101FD00012P)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 3 **Foam Dressing** (Basic UDI -DI: 69406101FD00022R)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 4 **Foam Dressing** (Basic UDI -DI: 69406101FD00032T)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Device 5 **Foam Dressing** (Basic UDI -DI: 69406101FD00042V)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 6 **Foam Dressing** (Basic UDI -DI: 69406101FD00052X)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 7 **Alginate Dressing** (Basic UDI -DI: 69406101AD0005YT)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 8 **Alginate Dressing** (Basic UDI -DI: 69406101AD0002YM)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 9 **Alginate Dressing** (Basic UDI -DI: 69406101AD0003YP)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 10 **Gelling Fiber Dressing** (Basic UDI -DI: 69406101GF00043Y)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 11 **Silicone Wound Contact Dressing** (Basic UDI -DI: 69406101SC00067X)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 12 **Silicone Wound Contact Dressing** (Basic UDI -DI: 69406101SC00027P)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 13 **Super absorbent dressing** (Basic UDI -DI: 69406101SP0001C4)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 14 **Super absorbent dressing** (Basic UDI -DI: 69406101SP0002C6)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 15 **Silicone Postoperative Dressing** (Basic UDI -DI: 69406101OP0009AY)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 16 **Medical Hydrogel Dressing** (Basic UDI -DI: 69406101HG00014J)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 17 **Medical Hydrogel Dressing** (Basic UDI -DI: 69406101HG00024L)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 18 **Amorphous Hydrogel Dressing** (Basic UDI -DI: 69406101AH00082G)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 19 **Amorphous Hydrogel Dressing** (Basic UDI -DI: 69406101AH000224)	☐ Class III ☐ Class IIb implantable ☒ Class IIb ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 065520 0034 Rev.02; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 20 **Nasal Dressing** (Basic UDI -DI: 69406101ND00015X)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 21 **Nasal Dressing** (Basic UDI -DI: 69406101ND00025Z)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 22 **Nasal Dressing** (Basic UDI -DI: 69406101ND000363)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 23 **Nasal Dressing** (Basic UDI -DI: 69406101ND000465)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 24 **Medical Sponges** (Basic UDI -DI: 69406101ES00017F)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 25 **Medical Sponges** (Basic UDI -DI: 69406101ES00027H)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 26 **Medical Sponges** (Basic UDI -DI: 69406101ET00017S)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 27 **Medical Sponges** (Basic UDI -DI: 69406101ET00027U)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 28 **Medical Sponges** (Basic UDI -DI: 69406101EW00018T)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 29 **Medical Sponges** (Basic UDI -DI: 69406101ED00012A)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 30 **Medical Sponges** (Basic UDI -DI: 69406101ED00022C)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 31 **Medical Sponges** (Basic UDI -DI: 69406101LS0001AA)	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 32 **Medical Sponges** (Basic UDI -DI: 69406101BT00016K	☐ Class III ☐ Class IIb implantable ☐ Class IIb ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 065520 0038 Rev.00; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023/08/24	713296586	Initial issue

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

We, as the manufacturer declare under our sole responsibility:

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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

- 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.

➢ **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.

Signed for and on behalf of the manufacturer:

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

Location & Date: Huizhou/ 2024-02-18

Signature: 张七

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电话：0752-5302000
传真：0752-5302020
邮编：516005
网址：www.foryoumedical.com

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)
Silicone Foam Dressing, **Super Absorbent 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**

Product name	**L&R REF Number**
Vliwasorb sensitive	141820
Vliwasorb sensitive	141821
Vliwasorb sensitive	141822
Vliwasorb sensitive	141823
Vliwasorb sensitive	141824
Vliwasorb sensitive	141825
Vliwasorb sensitive	141826
Vliwasorb sensitive	141828
Vliwasorb sensitive	141829
Vliwasorb sensitive	141830
Vliwasorb sensitive	141831
Vliwasorb sensitive	141832
Suprasorb P Heel	180040