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
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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

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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.

Signed for and on behalf of the manufacturer:

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

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Location & Date: Huizhou/ 2023-07-24

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)
Super Absorbent Dressing (product's trade name and number listed below is included in this device)	**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**

No.	PRODUCT NAME	SAP Item No.	ICC
1	CONVAMAX SUPABS N/ADH 7.5X7.5CM 1X10 INT	1727554	422566
2	CONVAMAX SUPABS N/ADH 10X10CM 1X10 INT	1727555	422567
3	CONVAMAX SUPABS N/ADH 10X20CM 1X10 INT	1727556	422568
4	CONVAMAX SUPABS NADH 12.5X12.5CM 1X10INT	1727557	422569
5	CONVAMAX SUPABS N/ADH 15X15CM 1X10 INT	1727558	422570
6	CONVAMAX SUPABS N/ADH 15X20CM 1X10 INT	1727559	422571
7	CONVAMAX SUPABS N/ADH 20X20CM 1X10 INT	1727560	422572
8	CONVAMAX SUPABS N/ADH 20X30CM 1X10 INT	1727561	422573
9	CONVAMAX SUPABS N/ADH 20X40CM 1X10 INT	1727562	422574
10	CONVAMAX SUPABS ADH 7.5X7.5CM 1X10 INT	1727563	422575
11	CONVAMAX SUPABS ADH 10X10CM 1X10 INT	1727564	422576
12	CONVAMAX SUPABS ADH 10X20CM 1X10 INT	1727565	422577

13	CONVAMAX SUPABS ADH 12.5X12.5CM 1X10 INT	1727566	422578
14	CONVAMAX SUPABS ADH 15X15CM 1X10 INT	1727567	422579
15	CONVAMAX SUPABS ADH 15X20CM 1X10 INT	1727568	422580
16	CONVAMAX SUPABS ADH 20X20CM 1X10 INT	1727569	422581
17	CONVAMAX SUPABS ADH 20X30CM 1X10 INT	1727570	422582
18	CONVAMAX SUPABS ADH 20X40CM 1X10 INT	1727571	422583
19	CONVAMAX SUPABS N/ADH 15X15CM 1X3 ES	1735278	423523
20	CONVAMAX SUPABS N/ADH 7.5X7.5CM 1X10 IN2	1737178	422566
21	CONVAMAX SUPABS N/ADH 10X10CM 1X10 IN2	1737179	422567
22	CONVAMAX SUPABS N/ADH 10X20CM 1X10 IN2	1737180	422568
23	CONVAMAX SUPABS NADH 12.5X12.5CM 1X10IN2	1737181	422569
24	CONVAMAX SUPABS N/ADH 15X15CM 1X10 IN2	1737182	422570
25	CONVAMAX SUPABS N/ADH 15X20CM 1X10 IN2	1737183	422571
26	CONVAMAX SUPABS N/ADH 20X20CM 1X10 IN2	1737184	422572
27	CONVAMAX SUPABS N/ADH 20X30CM 1X10 IN2	1737185	422573
28	CONVAMAX SUPABS N/ADH 20X40CM 1X10 IN2	1737186	422574
29	CONVAMAX SUPABS ADH 7.5X7.5CM 1X10 IN2	1737187	422575
30	CONVAMAX SUPABS ADH 10X10CM 1X10 IN2	1737188	422576
31	CONVAMAX SUPABS ADH 10X20CM 1X10 IN2	1737189	422577
32	CONVAMAX SUPABS ADH 12.5X12.5CM 1X10 IN2	1737190	422578
33	CONVAMAX SUPABS ADH 15X15CM 1X10 IN2	1737191	422579
34	CONVAMAX SUPABS ADH 15X20CM 1X10 IN2	1737192	422580
35	CONVAMAX SUPABS ADH 20X20CM 1X10 IN2	1737193	422581
36	CONVAMAX SUPABS ADH 20X30CM 1X10 IN2	1737194	422582
37	CONVAMAX SUPABS ADH 20X40CM 1X10 IN2	1737195	422583