Manufacturer's Declaration

March 13, 2024

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

- The validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (MDD Certificate) *and/or*
- 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	VHMED (Nantong) Co. Ltd.
Manufacturer Address	A1, 173 Ganjiang Road, Tongzhou Bay, Jiangsu, 226332 China
Single Registration Number (SRN)	CN-MF-000016558

Authorised Representative Name	Very Heal Ltd.
Authorised Representative Address	54 Bloomfield Ave, Belfast, BT5 5AD, Northern Ireland
Single Registration Number (SRN)	XI-AR-000037579

Notified Body Name	TÜV SÜD Product Service GmbH
Notified Body Address	Ridlerstrasse 65, 80339 München, Germany
Notified Body Number	0123
MDD Certificate Number(s) to Which This Declaration is Made	G1 certificate: No. G1 094490 0008 Rev.00 G2S certificate: No. G2S 094490 0005 Rev.00
MDD Certificate Issue Date(s)	2022-03-02
Original Expiry Date as Indicated on The Directive Certificate(s) Prior to The Extension of The Validity	G1 certificate: 2024-05-26 G2S certificate: 2023-11-07
Applicable end date of extended validity/transition period	31 December 2027/31 December 2028

We, as the manufacturer declare that the following conditions laid down in Regulation (EU) 2023/607 are met:

1. The Directive Certificate(s) for MDD Certificate [G1 certificate: No. G1 094490 0008 Rev.00; G2S certificate: No. G2S 094490 0005 Rev.00] were issued by TÜV SÜD Product Service GmbH in accordance with Directives 93/42/EEC after 25 May 2017 were still valid on 26 May 2021 and have not been withdrawn afterwards;

2. The devices under MDD Certificate [G1 certificate: No. G1 094490 0008 Rev.00; G2S certificate: No. G2S 094490 0005 Rev.00], listed in Schedule 1, continue to comply with Directive 93/42/EEC;

3. There are no significant changes in the design and intended purpose of the devices listed in Schedule 1;

4. The devices in Schedule 1 do not present an unacceptable risk to the health or safety of patients, users or other persons, or to aspects of the protection of public health;

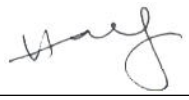
5. A Quality Management System has been put in place in accordance with Article 10(9) of Regulation (EU) 2017/745 no later than 26 May 2024;

6. A formal application has been lodged with TÜV SÜD Product Service GmbH on 7 September 2023 in accordance with Section 4.3, first subparagraph, of Annex VII of Regulation (EU) 2017/745 for conformity assessment for the devices listed in Schedule 1 or its/their substitutes, and a signed written agreement in accordance with Section 4.3, second subparagraph, of Annex VII of Regulation (EU) 2017/745 has been in place no later than 26 September 2024.

7. The requirements of Regulation (EU) 2017/745 relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices apply to the devices in Schedule 1.

Therefore, as per Article 1(1), paragraph (b) of Regulation (EU) 2023/607, the devices listed in Schedule 1 can be placed on the market or put into service in the EU market, and any other territories accepting of CE marked devices, until 31 December 2027/31 December 2028.

Signed for and behalf of the manufacturer:

Name: Haiying Wang	**Signature:** 
Title: General Manager	**Date:** 12/03/2024

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Schedule 1: Medical Device Information

Name of Devices	Device Class	MDD Certificate Number	End Date of Extended Validity/Transition Period
Monopolar Electrode Surgical Instrument	IIb	No. G1 094490 0008 Rev.00	31 December 2028
Bipolar Electrode Surgical Instrument	IIb	No. G1 094490 0008 Rev.00	31 December 2028
Hemostatic Ligation Clips	IIb	No. G1 094490 0008 Rev.00	31 December 2027
Veress Needle	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Suction and Irrigation Tube Set	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Trocar	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Specimen Retrieval Bag	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Wound Protection Retractor	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Insufflation Tube	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Port Closure Device	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Laparoscopic Instrument	IIa	No. G1 094490 0008 Rev.00	31 December 2028
Smoke Filter	Is	No. G2S 094490 0005 Rev.00	31 December 2028
Camera Cover	Is	No. G2S 094490 0005 Rev.00	31 December 2028