HSINER Co,. Ltd.
No. 312, Jhongshang Rd.
Shengang Dist.
Taichung City
429
Taiwan

03 July 2023

Notified Body Confirmation Letter

Reference: EU2023-607/627580

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has 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 following manufacturer:

HSINER Co,. Ltd.
No. 312, Jhongshang Rd.
Shengang Dist.
Taichung City
429
Taiwan

SRN Number: TW-MF-000007258

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of BSI Group The Netherlands B.V.,

Jen Wivholm

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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	Not Applicable	Not Applicable	Not Applicable

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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 at the pre-application stage)	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
Oxygen Mask/Venturi Mask/Face tent mask/High Concentration Oxygen Mask/Tracheostomy Mask/Nasal Cannula/Bubble Humidifier/Oxygen Tube/Diluter/Oxygen Adaptor/Swivel Oxygen Connector/Recovery Kit/Oxygen Enrich kit/High Flow Nasal Cannula **TD-02-OTA, BUDI: 47126880500007258OTASV**	Class IIa	MDD Name on certificate: Oxygen Therapy and Accessories	MDD Certificate: 10240-2017-CE-RGC-NA-PS Rev. 2.0 Expiry date 12/Nov/2023 NB number NB 2460 (DNV Product Assurance AS)
Nebulizing Set/Kit/Nebulizing Bottle/Aerosol Mask/Aerosol Chamber **TD-03-AT, BUDI: 47126880500007258ATGQ**	Class IIa	MDD Name on certificate: Aerosol Therapy	MDD Certificate: 10240-2017-CE-RGC-NA-PS Rev. 2.0 Expiry date 12/Nov/2023 NB number NB 2460 (DNV Product Assurance AS)
Anesthesia Circuit System/Breathing Circuit System/Air cushion mask/PVC Mask/Catheter Mount/Rebreathing Bag/Tubing/APL Valve/Elbow Connector/Wye Connector/Other Connector/Adjustable Valve/One-way	Class IIa	MDD Name on certificate: Anesthesia and Breathing Circuit System and Accessories (Single use)	MDD Certificate: 10240-2017-CE-RGC-NA-PS Rev. 2.0 Expiry date 12/Nov/2023 NB number NB 2460 (DNV Product Assurance AS)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Valve/Manifold/CO2 Sampling Line **TD-04-ABCSS, BUDI: 47126880500007258ABCSSGG**			
HME & HMEF **TD-06-HME, BUDI: 47126880500007258HMERD**	Class IIa	MDD Name on certificate: HME and HMEF	MDD Certificate: 10240-2017-CE-RGC-NA-PS Rev. 2.0 Expiry date 12/Nov/2023 NB number NB 2460 (DNV Product Assurance AS)
Filter **TD-07-FILTER, BUDI: 47126880500007258FILTER9V**	Class IIa	MDD Name on certificate: FILTER	MDD Certificate: 10240-2017-CE-RGC-NA-PS Rev. 2.0 Expiry date 12/Nov/2023 NB number NB 2460 (DNV Product Assurance AS)
Infant Nasal CPAP Mask/ Infant Nasal VPAP Mask/Infant CPAP Nasal Cannula **TD-08-INIV, BUDI: 47126880500007258INIV5S**	Class IIa	MDD Name on certificate: CPAP&VPAP Nasal Mask and Accessories	MDD Certificate: 10240-2017-CE-RGC-NA-PS Rev. 2.0 Expiry date 12/Nov/2023 NB number NB 2460 (DNV Product Assurance AS)

Confirmation Letter Revision History

Date	Action
03 July 2023	Initial issue

EC Certificate
Full Quality Assurance System

Certificate No.:
10240-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-21611-2007-PRC-RGC

Valid Until:
12 November 2023

This is to certify that the quality system of:

Hsiner Co., Ltd.
No. 312, Jhongshan Rd., Shengang District, Taichung City, Taiwan

For design, production and final product inspection/testing of:

Respiratory Devices

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 08 July 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Sholeh Gheissar

Sholeh Gheissar

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.:
10240-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-21611-2007-PRC-RGC

Valid Until:
12 November 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-06-17
1.0	Re-certification	2019-05-23
2.0	**Revise address**	**2019-07-08**

Products covered by this Certificate:

Product Description	Product Name	Class
Respiratory Devices	- CPAP and VPAP Face Mask and Accessories (Reusable) - Oxygen Therapy and Accessories - Aerosol Therapy Devices - Anaesthesia and Breathing Circuit System and Accessories (Reusable) - Resuscitator and Accessories (Reusable) - HME and HMEF - Filter - CPAP VPAP Nasal Mask and Accessories (Reusable) - Anaesthesia and Breathing Circuit System and Accessories (Single-use) - Resuscitator and Accessories (Single-use)	IIa

The complete list of devices is filed with the Notified Body

EC Certificate
Full Quality Assurance System

Certificate No.:
10240-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-21611-2007-PRC-RGC

Valid Until:
12 November 2023

Sites covered by this certificate

Site Name	Address
Hsiner Co., Ltd.	No. 312, Jhongshan Rd., Shengang District, Taichung City, Taiwan

EU Representative

Name	Address
mdi Europa GmbH	Langenhagener Strasse 71, 30855 Langenhagen, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate