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

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.,

Jennifer Wivholm
2023.07.03
16:43:53 -04'00'

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

Notified Body Confirmation Letter Reference: C548598

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, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 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, Jhongshan Rd., Shengang Dist., Taichung City 429, Taiwan
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 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 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

Place and date:
Høvik, 2023.09.21

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

- 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)

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 / Basic UDI-DI (under MDR application)	MDR Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
VPAP NASAL MASK/ Nasal Mask 47126880500007258NIVSZ	IIa	CPAP&VPAP Nasal Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
VPAP FACE MASK 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
CPAP FACE MASK/Standard Full Face Mask/Cirri Comfort Full Face Mask/Breeze Facial Comfort/BREEZE Zen Mask/ CPAP Pediatric Face Mask / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
CPAP NASAL MASK/Cirri Comfort Nasal Mask/Standard Nasal Mask/ Breeze Comfort Nasal mask/ Breeze Nasal mask/ Cirri Mini Comfort nasal mask / 47126880500007258NIVSZ	IIa	CPAP&VPAP Nasal Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
CPAP NASAL PILLOW MASK/Nasal Pillow 4in1 Mask/Breeze Pillow Mask / 47126880500007258NIVSZ	IIa	CPAP&VPAP NASAL Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
VPAP TOTAL FULL FACE MASK / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
CPAP TOTAL FULL FACE MASK / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Expiry date 12/Nov/2023
CPAP Tubing / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Pressure meter / 47126880500007258PMHP	IIa	Resuscitator and Accessories (Single use)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Anesthesia And Breathing Circuit (Reusable)/ Silicone smoothbore tube / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Silicone mask / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Silicone Rebreathing Bag / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Manual Resuscitator (Reusable) / 47126880500007258RARSM	IIa	Resuscitator and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
PEEP valve / 47126880500007258RARSM	IIa	Resuscitator and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Manual Resuscitator (Single-Use) / 47126880500007258RASSP	IIa	Resuscitator and Accessories (Single use)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
CPR mask/CPR face shield/CPR	IIa	Resuscitator and	Certificate number:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
pocket size resuscitator/CPR pocket size face shield / 47126880500007258RPACPRD5		Accessories (Single use)	10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
PEEP valve / 47126880500007258RASSP	IIa	Resuscitator and Accessories (Single use)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Pressure meter / 47126880500007258PMHP	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Silicone catheter mount/Double swivel silicone catheter mount / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023
Connector / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460 Expiry date 12/Nov/2023

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/21	C548598	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe

HSINER CO., LTD.
No.312, Jhongshan Rd., Shengang Dist.,
Taichung City 429, Taiwan R.O.C.
Tel:+886-4-25152480 Fax: +886-4-25152481
http://www.hsiner.com E-mail: sales@hsiner.com

Hsiner MDD Certificate Extension

Date: Sep 27, 2023

To whom it may concern,

Hsiner's CE certificate will be valid until Nov 12th, 2023. As we wouldn't be MDR certified before it expires, we applied to our notified body for MDR extension, and have received extension confirmation letter already.

We'll have two notified bodies for different product families after we get MDR certificates. Currently, there is no change of the CE number on labelling.

Additionally, Hsiner need to stop supplying certain devices after the current MDD certificate expires, which is Nov 12th, 2023, due to these devices will not be covered after transition to MDR. The detailed list of the available devices during transition will be provided upon request. Please contact the Marketing or RA team at Hsiner if there is further request.

Sincerely Yours,

Ben Lin / Vice General Manager

HSINER Co., Ltd.

HSINER CO., LTD.
No.312, Jhongshan Rd., Shengang Dist.,
Taichung City 429, Taiwan R.O.C.
Tel:+886-4-25152480 Fax: +886-4-25152481
http://www.hsiner.com E-mail: sales@hsiner.com

Manufacturer's Self-Declaration

in relation to Regulation 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 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- 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	Hsiner Co., Ltd.
Manufacturer address and contact details	No. 312, Jhongshan Rd., Shengang District, Taichung City, Taiwan
Single Registration Number (SRN) (if available)	TW-MF-000007258

Authorised Representative name (if applicable)	mdi Europa
Authorised Representative address and contact details	Langenhagener Strasse71, 30855 Langenhagen, Germany
Single Registration Number (SRN) (if available)	DE-AR-000006218

Notified body name (if applicable)	DNV Product Assurance AS and BSI Group The Netherlands B.V. □ See attached schedule
Notified body number (if applicable)	2460 and 2797 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	10240-2017-CE-RGC-NA-PS Rev. 2.0 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	12 Nov, 2023 □ See attached schedule
End date of extended validity/transition period	31 Dec, 2028 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

HSINER CO., LTD.
No.312, Jhongshan Rd., Shengang Dist.,
Taichung City 429, Taiwan R.O.C.
Tel:+886-4-25152480 Fax: +886-4-25152481
http://www.hsiner.com E-mail: sales@hsiner.com

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** 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 Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

■ Expired/expires *after* 20 March 2023:

■ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

■ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) 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:

Full Company Name ：Hsiner Co., Ltd.

Location & Date ：Taichung City, Taiwan 2023.08.15

Signature, Print Name, Title Phoebe Lu Phoebe Lu,Management representative

HSINER CO., LTD.
No.312, Jhongshan Rd., Shengang Dist.,
Taichung City 429, Taiwan R.O.C.
Tel:+886-4-25152480 Fax: +886-4-25152481
http://www.hsiner.com E-mail: sales@hsiner.com

Schedule of Devices

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

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
VPAP NASAL MASK/NIPPV Nasal Mask/Nasal Mask/Cirri Pediatric Oro-Nasal Mask non-vented/Nasal Mask non-vented/ Cirri Pediatric Nasal Mask non-vented / 47126880500007258NIVSZ	IIa	CPAP&VPAP Nasal Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
VPAP FACE MASK/NIPPV Full Face Mask/Full Face Mask/Cirri Comfort Full Face Mask NIPPV/Standard NIPPV Full Face Mask/ VPAP Pediatric Face Mask / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
CPAP FACE MASK/Standard Full Face Mask/Cirri Comfort Full Face Mask/Breeze Facial Comfort/BREEZE Zen Mask/ CPAP Pediatric Face Mask / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
CPAP NASAL MASK/Cirri Comfort Nasal Mask/Standard Nasal Mask/ Breeze Comfort Nasal mask/ Breeze Nasal mask/ Cirri Mini Comfort nasal mask / 47126880500007258NIVSZ	IIa	CPAP&VPAP Nasal Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**

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CPAP NASAL PILLOW MASK/Nasal Pillow 4in1 Mask/Breeze Pillow Mask / 47126880500007258NIVSZ	IIa	CPAP&VPAP NASAL Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
VPAP TOTAL FULL FACE MASK / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
CPAP TOTAL FULL FACE MASK / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
CPAP Tubing / 47126880500007258NIVSZ	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Pressure meter / 47126880500007258PMHP	IIa	Resuscitator and Accessories (Single use)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Anesthesia And Breathing Circuit (Reusable)/ Silicone smoothbore tube / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Silicone mask / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Silicone reservoir bag/Silicone Rebreathing Bag / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Manual Resuscitator (Reusable) / 47126880500007258RARSM	IIa	Resuscitator and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**

PEEP valve / 47126880500007258RARSM	IIa	Resuscitator and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Manual Resuscitator (Single-Use) / 47126880500007258RASSP / 47126880500007258RASSP	IIa	Resuscitator and Accessories (Single use)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
CPR mask/CPR face shield/CPR pocket size resuscitator/CPR pocket size face shield / 47126880500007258RPACPRD5	IIa	Resuscitator and Accessories (Single use)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
PEEP valve / 47126880500007258RASSP	IIa	Resuscitator and Accessories (Single use)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Pressure meter / 47126880500007258PMHP	IIa	CPAP&VPAP Face Mask and Accessories	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Silicone catheter mount/Double swivel silicone catheter mount / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**
Connector / 47126880500007258ABCSRGE	IIa	Anesthesia and Breathing Circuit System and Accessories (Reusable)	Certificate number: 10240-2017-CE-RGC-NA-PS Rev. 2.0 NB number NB 2460	Expiry date 12/Nov/2023	**31/Dec/2028**

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

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified by BSI 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** *MDD/AIMDD Certificate number, expiry date, NB number.*
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: 4712688050000725 8OTASV	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: 4712688050000725 8ATGQ	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 Valve/Manifold/CO2 Sampling Line TD-04-ABCSS, BUDI: 4712688050000725 8ABCSSGG	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)
HME & HMEF TD-06-HME, BUDI: 4712688050000725 8HMERD	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: 4712688050000725 8FILTER9V	Class IIa	MDD Name on certificate: FILTER	MDD Certificate: 10240-2017-CE-RGC-NA-PS Rev. 2.0 Expiry date 12/Nov/2023

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Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified by BSI 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** ***MDD/AIMDD Certificate number, expiry date, NB number.***
			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)