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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

Digitally signed by Durdun Margareta
Date: 2024.03.02 01:35:44 EET
Reason: MoldSign Signature
Location: Moldova

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