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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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