Notified Body Confirmation Letter Reference: C607215

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain 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:

BL Lifesciences Pvt. Ltd.

28-D, Sector 31, Ecotech I, Greater Noida,

Gautam Budh Nagar, U.P., India

SRN Number: **IN-MF-000015362**

The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR 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 120.3 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)

Place and date:
Høvik, 2023/05/23

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

Luis André Lourenco Fernandes
Management Representative

Table 1: Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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
Device 1 Brand Name: IpeX "Pressure Monitoring Kit/ Disposable Transducer Kits & Accessories" Basic UDI-8903283BKT-PMVX • Category: Infusion • Model/Variants- Single, Double, Triple- with/without Sampling Device/Sampling Stopcock	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 2 Brand Name: IpeX Pressure Monitoring Lines Basic UDI-8903283BPTHW • Category: Infusion • Model/Variants- Plain/Red/ Blue/Yellow	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 3 Brand Name: IpeX Extension Line/Infusion line with or without stopcock Basic UDI-8903283BEXH5 • Category: Infusion • Model/Variants- Clear/Red/Blue/Yellow-with or without Single /Double /Triple /Quadruple lumen.	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 4 Brand Name: PerfX Heart Lung Pack /Perfusion packs Basic UDI-8903283BHLGN • Category- Perfusion • Variants: With or without Arterial Filter	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 5 Brand Name: PerfX Cardioplegia Delivery System Basic UDI-8903283BCPGF • Category- Perfusion Variant: With or without Heat Exchanger/ Spiral	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 6 Brand Name: PerfX Arterial Filter	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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
Basic UDI-8903283BFL-AFQM • Category- Perfusion • Variant: Adult/Paediatric- With or without purge line			NB number NB: 2460 Expiry date: 12 -12-2022
Device 7 Brand Name: PerfX Hemoconcentrator Kit Basic UDI-8903283BHCG4 • Category- Perfusion • Variant: Adult /Pediatric/Infant	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 8 Brand Name: PerfX Connector Basic UDI-8903283BCNGB HLP Connector • Category- Perfusion Variant: Straight / Y connector - with/ without Luer Locks & caps	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 9 Brand Name: PerfX PVC Tubing Basic UDI-8903283BHL-TBSU • Category- Perfusion • Variant: PVC (Poly vinyl Chloride) / Silicon/Silicon replacement/Coated tubing	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 11 Brand Name: PerfX Tourniquet Set Basic UDI-8903283BTOU8L • Category- Perfusion • Variant: Adult /Pediatric	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 12 Brand Name: PerfX Mister Blower with or without handle Basic UDI-8903283BOTHT • Category- Perfusion Variant: with or without Tubing, should be able to blow the adequate quantity of CO2 and saline	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 13 Brand Name: AngiX Angio Kit /PTCA Kit & Accessories Basic UDI-8903283BKT-AKUE	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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
• Category- Cardiovascular • Variant: Angio Kit with/without Manifolds-2 gang kit/3 gang kit- with/without Drapes & Surgical instruments.			
Device 14 Brand Name: AngiX Manifold Basic UDI-8903283BMNF6G • Category- Cardiovascular • Variant: 2 Core/3 Core - Right ON/OFF	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 15 Brand Name: AngiX Introducer Needle Basic UDI-8903283BINGV • Category- Cardiovascular • Variant: Length-Variable - Size-18Ga /20Ga /21Ga/ 22Ga	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 16 Brand Name: AngiX Hemostasis Y Large Bore Basic UDI-8903283BHYL74 • Category- Cardiovascular • Variant: Large Bore rotating/ Click Type/ Push Pull	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 17 Brand Name: AngiX Control Syringe Basic UDI-8903283BCSR65 • Category- Cardiovascular • Variant: 6ml/10ml/12ml/20ml - Clear	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 18 Brand Name: AngiX High Pressure Tubing Basic UDI-8903283BHPT6R • Category- Cardiovascular • Variant: HPT-10/HPT-20/HPT-48 (HPT-XX) XX Denotes Length in inches - Tube Length- Variable	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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
Device 20 Brand Name: AngiX Inflation Device Basic UDI-8903283BIDG9 • Category- Cardiovascular • Variant: Straight/Gun Type	Is	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 21 Brand Name: SurgX Thoracic Drainage Catheter Basic UDI-8903283BTDC6F • Category- General Surgery • Variant: Straight & Angled - Tubing Length-45 cm	IIa	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 22 Brand Name: SurgX Cautery Tip Cleaner Basic UDI-8903283BOT-35T9 • Category- General Surgery • Variant: NA	Is	N/A	Certificate number: 10532-2017-CE-IND-NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 12 -12-2022
Device 23 Brand Name: VenX Central Venous Catheter Basic UDI-8903283BCVC5G • Category- Catheter • Variant: Single/ Double/ Triple/ Quadruple Lumen	III	N/A	Certificate number: 10533-2017-CE-IND-NAPS Rev. 2.0 NB number NB: 2460 Expiry date: 25-04-2023

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/23	C607215	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