Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din **29.09.2023**

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Terumo:

1. B-HL-4183
2. B-HL-4182

Se anexează următoarele acte:
1. Declarație de Conformitate
2. Certificatul de conformitate CE
3. Scrisoare de autorizare

Data **29.09.2023** Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Grabazei Alexandru
Date: 2023.09.29 16:06:54 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemitanu 17/6** tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Terumo:

1. B-HL-4183
2. B-HL-4182

Sunt autentice și corespund realității

Grabazei Alexandru, director general *Semnătura* _____

Data **29.09.2023**

Terumo Europe NV

Researchpark Haasrode 1520
Interleuvenlaan 40
3001 Leuven, Belgium
Tel.: +32 16 38 13 08
Fax: +32 16 38 16 01

www.terumo-europe.com

To: Whom It May Concern

Ref: 2023/108/CV/TF

Leuven, 15 September 2023

Power of Attorney

We, **Terumo Europe N.V.**, located at Interleuvenlaan 40, 3001 Leuven, Belgium, acting as the European Authorized Representative of the legal manufacturer BL Lifesciences PVT. LTD., located at 28-D, Sector-31, Ecotech-1, Greater Noida, Gautam Buddha Uttar Pradesh India, herewith authorize the company

FCPC "DataControl" SRL
20 Melestiu Street, MD-2001,
Chisinau, Republic of Moldova,

to register (re-register) the below-mentioned product in the Republic of Moldova:

Cardioplegia Delivery System
Heart Lung Pack
Hemoconcentrator Kit

In accordance with the conditions specified in the Distribution Agreement with an effective date 23 July 2018.

This authorization letter is valid for a period of 12 (twelve) months from the date of signature (date above) unless revoked earlier by Terumo Europe N.V.

Sincerely Yours,

Valérie Boydens
Director Regulatory Affairs

EC Certificate
Full Quality Assurance System

Certificate No.:
10532-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-03148-2007-PRC-IND

Valid Until:
12 December 2022

This is to certify that the quality system of:

BL Lifesciences Pvt. Ltd.
28-D, Sector 31, Ecotech I, Greater Noida,
Gautam Budh Nagar, U.P., India

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

Sterile Disposable Medical 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, 25 January 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Kolpus

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.:
10532-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-03148-2007-PRC-IND

Valid Until:
12 December 2022

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	Replaces certificate 3016-2007-CE-IND-NA rev. 6 (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460) at recertification	2017-12-12
1.0	Change of EU Representative and Brand Addition	2018-12-04
2.0	**Editorial Correction**	2019-01-25

Products covered by this Certificate:

Product Description	Product Name	Class
Infusion / Perfusion:		
Pressure Monitoring Kit / Disposable Transducer Kits & Accessories	Single/ Double/ Triple in Brand IPEX, ABMG, ACTIMED, QUALITY MEDICAL, SKY MEDICAL, CMI	IIa
Pressure Monitoring Lines	Plain/ Red/ Blue/ Yellow in Brand IPEX	IIa
Extension Line / Infusion line with or without Stopcock	In Brand IPEX	IIa
Heart Lung Pack / Perfusion packs	Adult / Paediatric with and without filter in Brand PERFX, MEM, NIPRO, TERUMO	IIa
Cardioplegia Delivery System	In Brand PERFX	IIa
Arterial Filter	Adult / Paediatric In Brand PERFX	IIa

Hemoconcentrator Kit	Adult / Paediatric in Brand PERFX	IIa
Connector	Straight / Y in Brand PERFX	IIa
PVC Tubing	In Brand PERFX	IIa
Suction Tubing	In Brand PERFX	IIa
Tourniquet Set	Adult / Paediatric in Brand PERFX	IIa
Mister Blower with or without Handle	In Brand PERFX, TERUMO	IIa
Cardiovascular:		
Angio kit / PTCA Kit & Accessories	In Brand ANGIX, ABMG	IIa
Manifold	1 core /2 Core / 3 Core /4 Core in Brand ANGIX	IIa
Introducer Needle	18G x 7cm / 21G x 4 cm / 20G x 4 cm in Brand ANGIX	IIa
Hemostatsis Y Large Bore	Large Bore / Click Type / Push Pull in Brand ANGIX	IIa
Control Syringe	10 ml /12 ml /20 ml in Brand ANGIX	IIa
High Pressure Tubing	In Brand ANGIX	IIa
Introducer Set	4F / 5F / 6F / 7F / 8F in Brand ANGIX	IIa
Inflation Device	30 Bar in Brand ANGIX	Is
General Surgery:		
Thoracic Drainage Catheter	16Fr / 20Fr / 24 Fr / 28 Fr / 32 Fr / 36 Fr in Brand SURGX	IIa
Cautery Tip Cleaner	In Brand SURGX	Is

The complete list of devices is filed with the Notified Body

EC Certificate
Full Quality Assurance System

Certificate No.:
10532-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-03148-2007-PRC-IND

Valid Until:
12 December 2022

Sites covered by this certificate

BL Lifesciences Pvt. Ltd. 28-D, Sector 31, Ecotech I, Greater Noida, Gautam Budh Nagar, U.P., India

EU Representative

Obelis s.a., Bd. Général Wahis 53, 1030 Brussels, Belgium, Tel: +(32).2.732.59.54,

Fax: +(32).2.732.60.03, Email: mail@obelis.net

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

	BL LIFESCIENCES PVT. LTD. **28-D, Sector-31, Ecotech-I, Greater Noida, Gautam Buddha Nagar, Uttar Pradesh-(India)**

DECLARATION OF CONFORMITY			
Document Ref. No.	INSP/F21	**Effective Date**	06-08-2020
Revision	01	**Page No.**	1 of 1

According to annex –II excluding section 4 of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices we: **BL Lifesciences Pvt. Ltd., 28-D, Sector-31, Ecotech-I, Greater Noida Gautam Budh Nagar, 201306, U.P., India.**

Declare under our sole responsibility that the product:

Brand	PerfX
Name of product Category	Heart Lung Pack
Name of product	Heart Lung Pack
Part No	BHL-XXXX
Classification	IIa, as per rule 2 of MDD 93/42/EEC, Annex IX, Meets the provisions of the MDD 93/42EEC & by amended directive 2007/47/EC concerning medical devices which apply to them

Meets the provisions of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices which apply to them:

We have presented our product as well as our quality management system to the notified body 'DNV_{2460}' for assessment as per the requirements of MDD 93/42/EEC as amended by 2007/47/EC.

Following standards were used to prove the products conformity with the essential requirements of the Directive:
[EN ISO 14971: 2012], [EN ISO 14155 (Part 1&2) : 2011],[EN 62366:2008], [EN ISO 10993 –1:2009 , 10993 –3:2014, 10993 –4:2009, 10993 –5:2009, 10993 –6:2009, 10993 –7:2010, 10993 –9:2009, 10993 –11:2009, 10993 –12:2009, 10993 –13:2010, 10993 –14:2009, 10993 –15:2009, 10993 –16:2010, 10993 –17:2009, 10993 –18:2009], [EN ISO 10993-10:2010],[EN ISO 10993-12:2012], [EN ISO 11607-1 :2009], [EN ISO 11607-2:2006], [[EN ISO 13485:2016], [ISO 14644 – 1 : 2015, 14644 – 2 : 2015], [EN ISO 15223:2016], [ISO 11137-1:2006], [ISO 11139:2006], [ISO 11135:2014], [ISO 11138-1:2009, 11138-2:2009, 11138-3:2009], [EN ISO 11140-1 :2009], [EN ISO 11135:2007], [IP -2017].

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

CE 2460

B L Lifesciences Pvt. Ltd.
28-D, Sector-31, Ecotech-I, Greater Noida,
Gautam Budh Nagar, 201306, U.P., India

EC REP
Obelis s.a,
Bd. General Wahis 53, 1030 Brussels, Belgium
Tel: + (32) 2.732.59.54, Fax: + (32) 2.732.60.03
Email: mail@obelis.net

NOTIFIED BODY:
DNV GL Presafe AS
Veritasveien 3, 1363 Høvik, Norway
Phone: +4767578800, Email: info@presafe.com
NOTIFIED BODY NO: 2460
CE Certificate No: 10532-2017-CE-IND-NA-PS Rev. 2.0
CE Certificate Valid up to: 12th December 2022

Priyanka Sachan
HOD Quality

BL Lifesciences Pvt. Ltd.

08/10/2020
Date of Issue

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