



Self-declaration of compliance towards transitional provisions under Regulation (EU) 2023/607 amending Regulations (EU) 2017/745

This Self Declaration is issued under the sole responsibility of [B L Lifesciences Pvt. Ltd., Site address: 28-D, Sector-31, Ecotech-I, Greater Noida, Gautam Buddha Nagar, Uttar Pradesh (India)-201306], it declares that the devices listed below are in conformity with the Regulation (EU) 2023/607 amending Regulations (EU) 2017/745, on medical devices.

Furthermore, B L Lifesciences Pvt. Ltd., explicitly declares that,

- a) Devices continue to comply with Directive 93/42/EEC.
- b) There are no significant changes in the design and intended purpose devices listed below
- c) The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health
- d) The certificates were valid on 26 May 2021 and have not been suspended nor withdrawn.

The certificate, for Class I & II, has expired on 12-12-2022, and the EU MDR agreement is in place (Copy enclosed)

For Class III, MDD certificate is valid till 25-04-2023. and the EU MDR agreement is also in place (Copy enclosed).

- e) has a quality management system in accordance with Article 10(9).
- f) requirements of Regulation (EU) 2017/745 relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are met.

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
Device 1 Brand Name: IpeX "Pressure Monitoring Kit/ Disposable Transducer Kits & Accessories" Basic UDI-8903283BKT-PMVX	Class 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-8903283BP THW	Class IIa	N/A	
Device 3 Brand Name: IpeX Extension Line/Infusion line with or without stopcock Basic UDI-8903283BEXH5	Class IIa	N/A	
Device 4 Brand Name: PerfX Heart Lung Pack /Perfusion packs Basic UDI-8903283BHLGN	Class IIa	N/A	
Device 5 Brand Name: PerfX Cardioplegia Delivery System Basic UDI-8903283BCPGF	Class IIa	N/A	

Manufacturing Unit : 28 D Sector 31 Ecotech I Greater Noida UP 201306 India Tel +91 120 4218028

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E-mail : blls@blllifesciences.com Website : www.blllifesciences.com CIN : U33112DL1999PTC098641



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 th NB Identification
Device 6 Brand Name: PerfX Arterial Filter Basic UDI-8903283BFL-AFQM	Class IIa	N/A	
Device 7 Brand Name: PerfX Hemoconcentrator Kit Basic UDI-8903283BHCG4	Class IIa	N/A	
Device 8 Brand Name: PerfX Connector Basic UDI-8903283BCNGB	Class IIa	N/A	
Device 9 Brand Name: PerfX PVC Tubing Basic UDI-8903283BHL-TBSU	Class IIa	N/A	
Device 10 Brand Name: PerfX Suction Tubing Basic UDI-8903283BSTJ7	Class IIa	N/A	
Device 11 Brand Name: PerfX Tourniquet Set Basic UDI-8903283BTOU8L	Class IIa	N/A	
Device 12 Brand Name: PerfX Mister Blower with or without handle Basic UDI-8903283BOTHT	Class IIa	N/A	
Device 13 Brand Name: AngiX Angio Kit /PTCA Kit & Accessories Basic UDI-8903283BKT-AKUE	Class IIa	N/A	
Device 14 Brand Name: AngiX Manifold Basic UDI-8903283BMNF6G	Class IIa	N/A	
Device 15 Brand Name: AngiX Introducer Needle Basic UDI-8903283BINGV	Class IIa	N/A	
Device 16 Brand Name: AngiX Hemostasis Y Large Bore Basic UDI-8903283BHYL74	Class IIa	N/A	
Device 17 Brand Name: AngiX Control Syringe Basic UDI-8903283BCSR65	Class IIa	N/A	
Device 18 Brand Name: AngiX High Pressure Tubing Basic UDI-8903283BHPT6R	Class IIa	N/A	

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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 th NB Identification
Device 20 Brand Name: AngiX Inflation Device Basic UDI-8903283BIDG9	Class Is	N/A	
Device 21 Brand Name: SurgX Thoracic Drainage Catheter Basic UDI-8903283BTDC6F	Class IIa	N/A	
Device 22 Brand Name: SurgX Cautery Tip Cleaner Basic UDI-8903283BOT-35T9	Class Is	N/A	
Device 23 Brand Name: VenX Central Venous Catheter Basic UDI-8903283BCVC5G	Class III	N/A	Certificate number: 10533-2017-CE-IND- NA-PS Rev. 2.0 NB number NB: 2460 Expiry date: 25-04- 2023

Date of Signature:

01-06-2023
DD-mm-YYYY

Place of Signature:

Greater Noida, India
Place, Country

Signed on behalf of B L Lifesciences Pvt. Ltd.

Nonita Kawatra
(Director Operations)



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