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

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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

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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