



EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000358096-PA-NA-IND

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

Valid Until:
27 May 2024

This is to certify that the quality system of:

B L Lifesciences Pvt. Ltd.

Corporate office: A-245, Okhla Industrial Area, Phase- I, New Delhi, 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, 24 May 2021

For the issuing office:
**Notified Body 2460
DNV Product Assurance AS**



Mariann Jeremiassen
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-11-MDD-f2, rev.0

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	Transfer of devices in certificate # 247266-2017-CE-IND-NA-PS Rev. 3.0 after name change due to merger of organization	2021-05-24

Products covered by this Certificate:

Product Description	Product Name	Class
Blood Bag with Anticoagulant Citrate Phosphate Dextrose Adenine Solution.	100, 250, 350, 450 and 500 ml/single, double, triple, quadruple and penta (with and without PDS safety features)	IIb
Blood Bag with Anticoagulant Citrate Phosphate Dextrose Solution.	100, 250, 350, 450 and 500 ml/single, double, triple, quadruple and penta (with and without PDS safety features)	IIb
Transfer Bag	100, 150, 200, 250, 300, 400 and 500 ml	IIb
Blood Bag with Anticoagulant CPD and Additive Solution SAGM	350 and 450 ml/Triple, Quadruple and Penta (with and without filter and PDS safety features)	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
B L Lifesciences Pvt. Ltd.	Corporate office: A-245, Okhla Industrial Area, Phase- I, New Delhi, India
B L Lifesciences Pvt. Ltd.	D-31, Site IV, UPSIDC Industrial Area, Greater Noida, Gautam Buddha Nagar, Uttar Pradesh (India) – 201306



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Place and date: Høvik, 24 May 2021

EU Representative

Obelis s.a, Bd. Général Wahis 53, 1030 Brussels, BELGIUM
Tel: + (32) 2 732 59 54, Fax: +(32) 2 732 60 03, E-Mail: 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 the Notified Body of any intended updating of the quality system and the Notified Body 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. the Notified Body 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.

End of Certificate