DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000322575-PA-NA-IND Rev.0.0	PRJC-502976-2014-MSL-IND	26 May 2024

This is to certify that the quality system of:

LARS MEDICARE PVT LTD.

Kila No. 16-17, Sultanpur Opp. Sports Authority of India, Near Bahalgarh Chowk
Sonepat-131021, Haryana, 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.

Digitally signed by Palii Nina
Date: 2022.07.06 14:54:07 EEST
Reason: MoldSign Signature
Location: Moldova

Place and date:
Høvik, 6 July 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.
10000322575-PA-NA-IND

Project No.:
PRJC-502976-2014-MSL-IND

Valid Until:
26 May 2024

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	Recertification Audit.	6 July 2020

Products covered by this Certificate:

Product Description	Product Name	Class
I.V. Cannula	With / Without wings &with/ without injection valve with / without safety. Without wings & without injection Valve Pen Type 14G,16G,17G,18G,20G,22G,24G & 26G	IIa
Infusion set	Infusion set with / Without flow regulator Infusion set with / without Micro drip Vented / Non Vented Infusion set with latex bulb Luer Slip with 21G needle. Vented / Non Vented Infusion Set with Y Site Luer lock with Needle 21G	IIa
Measured volume set	Measured volume set with / without flow regulator Measured volume set with Y Site with Luer Lock Needle 23G 100ml, 110 ml, 150 ml	IIa
Blood transfusion set	Single / Double chamber with / without Airway. Blood transfusion set with Airvent with Y Site with Needle 18G. Vented / Non Vented blood transfusion set with latex bulb Luer Slip with 18G needle. Vented / Non Vented blood transfusion Set with Y Site Luer lock with Needle 18G	IIa

Extension tubing	High pressure extension line With / without flow regulator 10cm, 25cm, 50cm, 100cm, 150cm, 200cm, 250cm, 300cm	IIa
Three Way Stop Cock With/Without Extension tubing	Non Lipid /Lipid Resistant	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
LARS MEDICARE PVT LTD.	Kila No. 16-17, Sultanpur Opp. Sports Authority of India, Near Bahalgarh Chowk Sonepat-131021, Haryana, India

EU Representative

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Certificate No.	Project No.:	Valid Until:
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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