



# DNV BUSINESS ASSURANCE

## EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 162562-2014-CE-IND-NA 0.0

This Certificate consists of 4 pages

*This is to certify that the Quality Management System of*

### **LARS MEDICARE PVT. LTD.**

Kila No. 16-17, Sultanpur, Opp. Sports Authority of India,  
Near Bahalgarh Chowk, Sonapat – 131 021, 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 Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

*Further details are given overleaf*

*Place and date:*

Høvik, 09 September

For DET NORSKE VERITAS CERTIFICATION AS  
NORWAY

Alexey Shiryaev  
Certification Manager



Notified Body No.:  
0434

*This Certificate is valid until:*

**01 August 2019**

Aud Løken Eiklid  
Technical Reviewer

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://www.dnv.com/digitalsignatures) for more info*

**Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.**

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300,000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 162562-2014-CE-IND-NA  
 Rev. No.: 0.0  
 Project No.: PRJC-502976-2014-MSL-IND

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

## Certificate history

Revision	Description	Issue Date
0	Original certificate	2014-08-01

## Products covered by this Certificate

Product Description	Product	Class
<b><u>For Anaesthesia Procedure</u></b>		
Nebulizer with Mask	Adult, Neo	IIa
Catheter Mount	Expandable, Normal	IIa
HME Filter	Ported, Non Ported	IIa
Respiratory Circuit	Expandable, Normal for Adults & Paediatric	IIa
Twin Bore Nasal Catheter	Adult, Pediatric, Neonatal	IIa
Oxygen Mask	Adult, Neo	IIa
<b><u>For General Surgery Procedure</u></b>		
Yankauer Suction Set	Plain Tip, Crown Tip	IIa
Surgical Gloves	Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5	IIa
Examination Gloves	Extra Small, Small, Medium, Large, Extra Large	Is
IV Fixation Dressing		Is
<b><u>For Infusion Procedure</u></b>		
I.V. Infusion Set	With or Without Airway 20 & 60drops/ml	IIa
Measured Volume Set	Size- 110 ml, 150 ml	IIa
Blood Transfusion Set	Single chamber with/without Airway Double chamber with/without Airway	IIa
I.V. Cannula	With Wings & With Injection Port, With Wing & Without Injection Port, Without wing & Without Injection Port, Size - 14, 16, 17, 18, 20, 22, 24, 26G	IIa
3-Way Stopcock	Standard, Lipid Resistant	IIa
3-Way Stopcock with Extension Tubing	Standard, Lipid Resistant in 10, 15, 25, 50, 75, 100, 125, 150, 200, 250, 300 cm	IIa
Extension Tubing	Size - 10, 15, 25, 50, 75, 100, 125, 150, 200, 250, 300 cm	IIa



Cert. No.: 162562-2014-CE-IND-NA  
Rev. No.: 0.0  
Project No.: PRJC-502976-2014-MSL-IND

AV Fistula Needle	Twin set, Single Size – 15,16,17 G	IIa
Luer Lock	Standard	Is
Injection stopper	Latex & Latex Free	Is
Safety IV Cannula	With Wings & With Injection Port, With Wing & Without Injection Port, Without wing & Without Injection Port, Size - 14, 16, 17, 18, 20, 22, 24 G	IIa
I.V. Flow Regulator	Standard	IIa
Hypodermic Syringe with Needle	1ml, 3ml, 5ml, 10ml	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, Sonapat – 131 021, Haryana, India.

#### EU Representative

mdi Europa GmbH, Langenhagener Strasse 71, D 30855 Langenhagen



Cert. No.: 162562-2014-CE-IND-NA  
Rev. No.: 0.0  
Project No.: PRJC-502976-2014-MSL-IND

## 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 local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE