Digitally signed by Jighili Tatiana
Date: 2019.02.15 10:23:42 EET
Reason: MoldSign Signature
Location: Moldova

Certificate of CE-Registration

mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG) für den Hersteller

LARS MEDICARE PVT. LTD.
Kila No. 16 & 17
Village: Sultanpur
Opp. Sports Authority of India, Bahalgarh Chowk,
Sonipat – 131201 Haryana
India

as stipulated and demanded by the aforementioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

Medical Device	UMDNS Code	Registration-No.

see attached list

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG.

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

November 2014

Werner Sander
President & CEO

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
247224-2017-CE-IND-NA-PS	PRJC-502976-2014-MSL-IND	**01 August 2019**

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
247224-2017-CE-IND-NA-PS	PRJC-502976-2014-MSL-IND	01 August 2019

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 – 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 H2) 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, 10 October 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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

Certificate of CE-Registration

mdEuropa

Attachment to Certificate of CE Registration for Lars Medicare

Medical Device	UMDNS Code	Registration-No.
I.V. Cannula / I. V. Safety Cannula	10582 – Class IIa	DE/CA09/0760/761-A2
3-Way Stop Cock	13803 – Class IIa	DE/CA09/0760/762-A2
3-Way Stop Cock with extension Tube	16387 – Class IIa	DE/CA09/0760/763-A2
Extension Tube	12170 – Class IIa	DE/CA09/0760/764-A2
A.V. Fistula	13121 – Class IIa	DE/CA09/0760/765-A2
Luer Lock	11729 – Class Is	DE/CA09/0760/766-A2
Surgical Gloves	11883 – Class IIa	DE/CA09/0760/878-A2
Examination Gloves	11882 – Class Is	DE/CA09/0760/879-A2
Measured Volume Set	12159 – Class IIa	DE/CA09/0760/1300
I.V. Infusion Set	12157 – Class IIa	DE/CA09/0760/1301
Blood Transfusion Set	10421 – Class IIa	DE/CA09/0760/1302
Hypodermic Syringe With Needle	13940 – Class IIa	DE/CA09/0760/1303
I.V. Flow Regulator	16789 – Class IIa	DE/CA09/0760/1304
Injection Stopper	12129 – Class Is	DE/CA09/0760/1305
Yankaur Suction Set	13-846 – Class IIa	DE/CA09/0760/1311
I.V. Fixation Dressing	11-324 – Class Is	DE/CA09/0760/1312
HME Filter	14-352 – Class IIa	DE/CA09/0760/1314
Nebulizer with Mask	12-449 – Class IIa	DE/CA09/0760/1315
Catheter Mount	17-551 – Class IIa	DE/CA09/0760/1316
Respiratory Circuit	15-003 – Class IIa	DE/CA09/0760/1317
Twin Bore Nasal Catheter	12-700 – Class IIa	DE/CA09/0760/1318
Oxygen Mask	12-448 – Class IIa	DE/CA09/0760/1321

November 2014

Werner Sander
President & CEO

TRIUMF-MOTIV S.R.L. 1012600021180 REPUBLICA MOLDOVA, MUN. CHISINAU SOCIETATEA CU RASPUNDERE LIMITATA