

DECLARATION OF CONFORMITY

Name of Device : I.V. Infusion Set
Description : Intravenous Infusion Set
Specification : 14 mm Chamber, Vented, Bulb latex, Luer Slip with Needle PE pouch pack
UMDNS Code : 12157
Classification : Class II a

Manufacturer Name and Address.

LARS MEDICARE PRIVATE LIMITED,
Kila No. : 16 - 17, Sultanpur,
Opp. Sports Authority of India, Near Bahalgarh Chowk,
Sonapat -131 021, (Haryana), INDIA.

Management Representative- Mr. Anoop Batra

M/s Lars Medicare address of the facility as mentioned above hereby declare that the Medical device I.V. Infusion Set confirms with the essential requirements and provisions of Council Directive 93/42/EEC (amended by directive 2007/47/EC) & are Subject to the procedure set out in Annex VII combine with Annex II (excluding Section 4) of the European Council Directive 93/42/EEC (excluding Point 4) (amended by directive 2007/47/EC) under the supervision of

Notified Body No ^{CE}2460 DNVGL NEMKO PRESAFE AS
Veritasveien 3
1363 Horik, Norway

The declaration is supported by the quality management system certification based on EN ISO 13485:2016

Applicable Standards: - EN ISO 14971:2012, EN ISO 14155:2011/AC, EN 62366:2008, EN ISO 10993-1:2020, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-7:2009, ISO 10993-10:2010, EN ISO 10993-9:2009, EN ISO 10993-11:2018, EN ISO 10993-17:2009, EN ISO 10993-18:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, ISO 80369-7:2016, EN ISO 11138-2:2009, EN ISO 11140-1: 2014, EN ISO 11737-1:2009, EN ISO 11737-2:2020, EN ISO 11135-1:2014, EN 1422: 2009, EN ISO 15223-1:2016, EN ISO 556:2006, EN 1707 : 1996, EN 1041:2008, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-3:2005, ISO 14644-4:2001, ISO 14644-5:2004, ISO 14644-6:2007, ISO 14644-9:2012, ISO 14644-10:2013, BS EN 868-5:2018, EN ISO 13868: 2002, ISO 9626: 2016, ISO 8536-4:2019, ISO 11135:2014

European Authorized Representative established within EU:

☒ **EC REP** mdi Europa GmbH, Langenhagener Strasse D- 71, 30855 Lagenhagen, Germany.

Contact Person: Mr. Verner Sander

* Designation: President & CEO

* Fax. No.: +49 511 39 08 95 39

* E-mail: info@mdi-europa.com

Signature



Name: - Anoop Batra

**Position: - Manager-Quality Assurance
Regulatory Affairs & MR**

Date: 02.04.2021



An EN ISO 13485:2016 & CE Certified

Marketing Office: 136, 2nd Floor, Avtar Enclave, Paschim Vihar, Rohtak Road, New Delhi-110063 India

Tel.: +91-11-45733068, **Telefax:** +91-11-45652878, **GST No.:** 07AABCL1302Q12K

Works: Kila No.: 16-17, Sultanpur, Opp. Sports Authority of India, Near Bahalgarh Chowk, Sonapat-131 021, Haryana, India,

Tel.: +91-8930111190, 8930111006, **GST No.:** 06AABCL1302Q12M

E-mail: mkt@larsmedicare.com / plant@larsmedicare.com, **Website :** www.larsmedicare.com