

EC Certificate

Full Quality Assurance System

Certificate No.:
11168-2017-CE-IND-NA-PS Rev. 0.0

Project No.:
PRJC-503753-2014-MSL-IND

Valid Until:
04 March 2020

This is to certify that the quality system of:

Harsoria Healthcare Pvt. Ltd.

**110 – 111, Phase – IV, Udyog Vihar,
Gurgaon – 122 015, 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, 12 October 2017



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.

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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	Supersedes DNVGL (NB 0434) Certificate no: 5262-2014-CE-IND-NA 0.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-12

Products covered by this Certificate:

Product Description	Product Name	Class
IV Cannula with Catheter with or without injection valve and with or without wings	Sizes 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Safety IV Cannula with Catheter with or without injection valve and with or without wings	Sizes 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
AV Fistula Needle Set	Variant- Twin Set, Single in Size- 14G, 15G, 16G, 17G, 18G	IIa
Injection Stopper		IIa
3 Way Stop Cock with/without Extension Tubes	Lipid/Non-Lipid Resistant with Tube Length 10cm, 50cm, 100cm, 150cm, 200cm, 250cm	IIa
Extension Tube	10cm, 25cm, 50cm, 75cm, 100cm, 150cm, 200cm, 250cm	IIa
Flow Regulator		IIa
Luer Cap		IIa
Combi Luer Lock		IIa
Obturator	12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Intravenous Infusion Set (I.V. Set)	With or without Air Vent, Luer Lock and Flow Regulator	IIa

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Blood Transfusion Set (B.T. Set)	Variant - Single chamber with/without Air Vent	IIa
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The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Harsoria Healthcare Pvt. Ltd.	110 – 111, Phase – IV, Udyog Vihar, Gurgaon – 122 015, Haryana, India.

EU Representative

mdi Europa GmbH, Langenhagener Strasse 71, D 30855, Hannover-Langenhagen, Germany
email: info@mdi-europa.com

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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