DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
11168-2017-CE-IND-NA-PS Rev 1.0	PRJC-503753-2014-MSL-IND	27 May 2024

This is to certify that the quality system of:

Harsoria Healthcare Pvt. Ltd.

110-111, UDYOG VIHAR PHASE-4, GURUGRAM-122015, HARYANA, INDIA

For design, production and final product inspection/testing of:

STERILE MEDICAL DEVICES FOR INFUSION AND TRANSFUSION THERAPY

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.

Signed by / Podpisano przez:

Radosław Żywicki

Date / Data:
2023-10-18 08:58

Place and date:
Høvik, 14 July 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Palani Damodharan

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

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om MedisinskUtstyr" 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
1.0	**Recertification**	2020-07-14

Products covered by this Certificate:

Product Description	Product Name	Class
Intravascular Catheter / IV Catheter / IV Cannula	Sizes 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Safety IV Cannula/ Safety IV Catheter	Sizes 14G, 16G, 17G, 18G, 20G, 22G, 24G	IIa
Arterial Venous Fistula Needle Set	Sizes: 14G, 15G, 16G, 17G, 18G	IIa
Three Way Stopcock/3-Way Stopcock with Extension Tube	Tube Length 5 cm - 300 cm	IIa
Extension Tube/ Extension Tubing Set	Tube Length 5 cm - 300 cm	IIa
IV Flow Regulator / Flow Regulator / Flow Regulator Set		IIa
Injection Stopper / Heparin Lock		IIa
Combi Luer Lock		IIa
Luer Cap / Threaded Stopper		IIa

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Site Name	Address
Harsoria Healthcare Pvt. Ltd.	110-111, UDYOG VIHAR PHASE-4, GURUGRAM-122015, HARYANA, INDIA

EU Representative
mdi Europa GmbH
Langenhagener Str. 71
D-30855 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