

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 10000322040-PA-NA-IND

Project No.: PRJC-594542-2019-PRC-IND

Valid Until: 26 May 2024

This is to certify that the quality system of:

HARSORIA HEALTHCARE PVT. LTD., UNIT-2

KK 83/85, KH NO. 342/266, Saraj Majra Gujran, Baddi-Jharmajri Road, Baddi, Distt. Solan,
Himachal Pradesh, INDIA-173205

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.

Place and date:
Høvik, 18 May 2021

Check Validity

For the issuing office:
**Notified Body 2460
DNV Product Assurance AS**



Hazem Tinawi
Technical Reviewer

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

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	Original Certificate	18 May 2021

Products covered by this Certificate:

Product Name	Product Description	Class
Intravascular Catheter / IV Catheter / IV Cannula With or without injection port and with or without wings	Size: 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G.	IIa
Three Way Stopcock / Three-Way Stopcock with Extension Tube	Tube Length: 10cm, 25cm, 50 cm, 75cm, 100cm, 150cm, 200cm, 250cm.	IIa
Extension Tube / Extension Tubing Set	Tube Length: 10cm, 25cm, 50 cm, 75cm, 100cm, 150cm, 200cm, 250cm.	IIa
I.V. Set / IV Set / IV Giving Set / Intravenous Infusion Set / Infusion Set	Adult and Paediatric	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
HARSORIA HEALTHCARE PVT. LTD., UNIT-2	KK 83/85, KH NO. 342/266, Saraj Majra Gujran, Baddi-Jharmajri Road, Baddi, Distt. Solan, Himachal Pradesh, INDIA-173205

EU Representative

Mdi Europa GmbH, Langenhagener Str. 71, D-30855 Langenhagen, Germany.

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 Notified Body of any intended updating of the quality system and the Notified Body 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. the Notified Body 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.

End of Certificate