



America

CERTIFICATE

No. QS6 107353 0001 Rev. 00

Certificate Holder: **Harsoria Healthcare Pvt. Ltd**
110-111 Udyog Vihar Phase-4
Gurgaon, Haryana 122015
INDIA

Certification Mark:



Scope of Certificate: **Design, Development, Manufacture, Production and Distribution of Catheters, Intravenous Infusion Set, Extension Set, Oxygen Mask, Nasal Cannula, Nebulizer Mask used in Infusion, Transfusion and Respiratory Therapy**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005887**

Effective Date: **2022-08-10**

Expiry Date: **2025-08-09**

Page 1 of 3

Date of Issue: 2022-08-17

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820
 - 21 CFR Part 821

Facility(ies):

Harsoria Healthcare Pvt. Ltd
 110-111 Udyog Vihar Phase-4, Gurgaon, Haryana 122015,
 INDIA

Harsoria Healthcare Pvt. Ltd. Unit-2
 KK 83/85, Kh No. 342/266 Saraj Majra, Gujran, Baddi-Jharmajri
 Road, Distt. Solan, Himachal Pradesh, Baddi 173205, INDIA

Page 2 of 3

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Facility Scopes:

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Page 3 of 3

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