

| evaluate | assess | certify |



assessors of quality

Certificate No. MD-QMS/91/R/2578/a

This is to certify that

SURU International Pvt. Ltd.

**Main Office : C/6, Sona Udyog Wing 3, Parsi Panchayat Road, Andheri (E),
Mumbai – 400 069, Maharashtra, India**

(a list of certified workplaces is contained in Annexure which is inseparable part of this Certificate)

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard

ISO 13485:2016

This certificate is valid for the following scope :

**Design, Manufacture and Supply of
I. Non Active Medical Devices :**

- Infusion Therapy (including IV Catheters) Devices
- Central Venous Access Devices
- Anesthesia and Respiratory Care Devices
- Disposable Devices for Urology
- Disposable Devices for Gastroenterology
- Blood Management System Devices
- Devices for Wound Care :
- Surgical Sutures and Mesh
- Surgical and Wound Care Devices

Initial Certification : 17/04/2018

Valid until : 16/04/2021

Modified on : 18/08/2018

(Replaces withdrawn Certificate No. MD-QMS/91/R/2578 issued on 17th April, 2018)



ACCREDITED[®]
Management Systems
Certification Body

Authorised Signatory

The authenticity of this document may be re-affirmed by writing to certification@zenith-worldwide.com. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law.

Accreditation Body: International Accreditation Service, Inc.
3060 Saturn Street, Suite 100, Brea, California 92621-1732 U.S.A.
www.iasonline.org (ULC Code MSCB-128-9559)

Issuing authority: Zenith Quality Assessors Pvt. Ltd. - MSCD001
306, 4th Floor, Sai Apex, Viman Nagar, Pune-411014, Maharashtra, India
www.zenith-worldwide.com

CI/ASMDQMS/ISMS/01/20117 (Cl.8.2)



Annexure to Certificate No. MD-QMS/91/R/2578/a

Issued to the Company

SURU International Pvt. Ltd.

Main Office : C/6, Sona Udyog Wing 3, Parsi Panchayat Road, Andheri (E),
Mumbai – 400 069, Maharashtra, India

Scope of activities :

-Management, Human Resource, Administration, Marketing, Sales, Purchase of

I. Non Active Medical Devices :

- Infusion Therapy (including IV Catheters) Devices
- Central Venous Access Devices
- Anesthesia and Respiratory Care Devices
- Disposable Devices for Urology
- Disposable Devices for Gastroenterology
- Blood Management System Devices

II. Devices for Wound Care :

- Surgical Sutures and Mesh
- Surgery and Wound Care Devices

SURU International Pvt. Ltd.

Factory : Plot # 5, Poonarnia Comp., Saravali, Jawhar Road, Dahanu - 401 602,
Maharashtra, India

Scope of activities :

-Design and Development, Sterilization, Production, Quality Control, Stores and

Dispatch of

I. Non Active Medical Devices :

- Infusion Therapy (including IV Catheters) Devices
- Central Venous Access Devices
- Anesthesia and Respiratory Care Devices
- Disposable Devices for Urology
- Disposable Devices for Gastroenterology
- Blood Management System Devices

II. Devices for Wound Care :

- Surgical Sutures and Mesh
- Surgery and Wound Care Devices

Initial Certification : 17/04/2018

Valid until : 16/04/2021

Modified on : 18/08/2018

(Replaces withdrawn Certificate No. MD-QMS/91/R/2578 issued on 17th April, 2018)

A handwritten signature in black ink, appearing to read 'Sundar', is written over a horizontal line.

Authorised Signatory

Accreditation Body: **International Accreditation Service, Inc.**
3060 Saturn Street, Suite 100, Brea, California 92821-1732 U.S.A
www.iasonline.org (IUC Code MSCB-128-9559)

Issuing authority: **Zentih Quality Assessors Pvt. Ltd. - MSCD001**
306, 4th Floor, Sai Apex, Vimannagar, Pune-411014, Maharashtra, India
www.zentih-worldwide.com

EC Certificate Full Quality Assurance System: IN99/50609

The management system of

SURU International Pvt. Limited

Plot # 5, Poonamia Compound, Saravali, Jawhar Road, Dahanu,
Dist. Palghar, Maharashtra - 401 602, India

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 March 2018 until 23 April 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 25 February 2020
Issue 1. Certified since 11 June 1999

Certification is based on reports numbered INMUM 235591

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd Systems & Services Certification
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t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

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SURU International Pvt. Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

**SURUSPIN Sterile L P Spinal Needles
SURU CENOCATH Sterile Central Venous Catheter / Kits**

Infusion Therapy: Sterile I.V. Cannula, Sterile Stop Cock with or without Extension Tube (Three Way / Four Way / Manifolds), Sterile Extension Line / Connecting Tube / Set, Sterile Infusion Set (Adult / Paediatric / Huber), Sterile Flow Regulator (I.V.) with / without Extension Tube, Sterile Burette Set (Paediatric Drip Set / Measured Volume Drip Set), Sterile Stylet (Obturator / Mandrin), Sterile Peritoneal Dialysis Transfusion Set , Sterile Peritoneal Dialysis Catheter Kit, Sterile Scalp Vein Butterfly Set (Safety Winged Infusion Set), Sterile Syringes with needle(Single Use Syringe / Safety Syringe (Auto Disable Syringe) / Insulin Syringe J, Sterile Disposable Needles (Sterile Chiba Needle / Sterile Dental Needle / Sterile Biopsy Needle / Sterile Bone Marrow Needle / Sterile Introducer Needle / Sterile Seldinger Introducer Needle / Sterile Initial Puncture Needle / Sterile Metal Suction Needle / Sterile Blunt End Needle / Sterile Speciality Needle / Sterile Hypodermic Needle), Sterile Luer Lock, Sterile Disposable Needleless Connector, Sterile CVP Manometer.

Anaesthesia & Respiratory Care: Sterile Nasal Oxygen Catheter, Sterile Oxygen Mask (Oxygen Face Mask), Sterile Nebulizer Mask / Kit, Sterile Venturi Mask Set / Kit, Sterile Suction Catheter / Endobronchial Tube, Sterile Oxygen Set (Twin Bore Nasal Oxygen Set), Sterile Yankaur Suction Set (Vacuum Suction Set), Sterile Airways (Guedel Airways / Nasopharyngeal Airways / Oropharyngeal Airways), Sterile Endotracheal Tube (Plain / Cuffed / Reinforced), Sterile Epidural Needle, Sterile Flexible Catheter Mount, Sterile Oxygen Recovery "T" Kit, Sterile Breathing System (Breathing Circuit with / without HME filter), Sterile Epidural Catheter / Set / Kit.

SURU International Pvt. Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

Urology: Sterile Nelaton Urinary Catheter / Nelaton Catheter / Urethral Catheter / Urethral Catheter and Kit, Sterile Female Catheter, Sterile Foley Balloon Catheter / Foley Urinary Catheter (Latex / 100% Silicon / All Silicon), Sterile Male External Catheter, Sterile Malecot Catheter.

Gastroenterology: Sterile Adult Feeding Tube (Sterile Ryle's Tube, Sterile Levin's Tube (Stomach Tube)), Sterile Infant Feeding Tube, Sterile Infant Mucus Extractor, Sterile Enteral Feeding Bag, Sterile Salem Sump Tube / Irrigation Tube

Surgery & Wound Care: Sterile Thoracic Drainage Catheter with / without Trocar (Chest Drainage Catheter / Pleural Catheter), Sterile Skin Stapler, Sterile Water Sealed Drainage Set (Intra Costal Drainage Bag), Sterile Abdominal Drain Catheter / Set, Sterile Supra Pubic Drainage Catheter

Blood Management System: Sterile Transfusion Sets (Blood Transfusion Set) / Blood Lines (Haemodialysis Blood Tubing Set)

Other Products: Sterile Kehr's "T" Tube, Sterile Tracheostomy Tube, Sterile A. V. Fistula Needle, Sterile Colostomy Bag / Kit.