

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 IN/MUM 235591

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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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), 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

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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.