

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 05 September 2020 until 24 May 2024  
and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 11 June 1999  
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered IN/MUM 235591

Authorised by



SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4 EN rev. 02

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# SURU International Pvt. Limited

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

**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.

**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.

**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, Sterile Rectal Catheter 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, Sterile Closed Wound Suction Drainage Unit / Vacuum Drainage Bottle (Low / Medium / High Pressure) with / without Redon Drain Catheter, Sterile Corrugated Drainage Sheet

**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

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.



## SURU International Pvt. Ltd

Plot # 5 Poonamia Compound, Saravali, Jawhar Road,  
Dahanu, Dist.: Palghar, Maharashtra - 401602, India

### Scope:

**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.

**Urology:** Sterile Nelaton Urinary Catheter / Nelaton Catheter / Urethral Catheter / Urethral Catheter and Kit, Sterile Female Catheter, Sterile Foley Balloon Catheter /

Authorised by



Global Medical Devices Certification Manager

## SGS Belgium NV, Notified Body 1639

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SGS Belgium NV

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Foley Urinary Catheter (Latex / 100% Silicon / All Silicon), Sterile Male External 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, Sterile Rectal Catheter

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, Sterile Closed Wound Suction Drainage Unit / Vacuum Drainage Bottle (Low / Medium / High Pressure) with / without Redon Drain Catheter, Sterile Corrugated Drainage Sheet

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

This corrigendum is only valid together with accompanying 93/42/EEC certificate  
Issue 3

Correction Date	Correction
Change approved by SGS on 23 August 2022	Describe here clearly the correction: Addition of new plot and the address is "Plot # 5,6, Poonamia Compound, Saravali, Jawhar Road, Dahanu, Dist.: Palghar, Maharashtra - 401602, India

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