



Certificate IN14/91658

The management system of

# MAIS India Medical Devices Pvt. Ltd

525 P, Sector- 37 Pace City II, Gurgaon - 122001, Haryana, India

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design and manufacture of sterile & non-sterile disposable medical devices for Infusion Therapy, Anaesthesia & Respiratory care, Surgery & Wound Care & Urology**

This certificate is valid from 27 April 2020 until 17 July 2023 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 18 March 2023  
Issue 3. Certified since 17 July 2014



Authorised by



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EC Certificate Full Quality Assurance System: Certificate IN18/818843208

The management system of

# MAIS India Medical Devices Pvt. Ltd.

525 P, Sector- 37, Pace City II, Gurgaon - 122001, Haryana, 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 03 January 2018 until 17 July 2022  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 18 March 2020

Issue 1. Certified since 17 July 2014

Certification is based on reports numbered IN/GUR 235605

Authorised by

### SGS United Kingdom Ltd, Notified Body 0120

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# MAIS India Medical Devices Pvt. Ltd.

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

Issue 2

Detailed scope

**Infusion Therapy: Sterile I.V. Cannula / I.V. Catheter (With or Without Safety Feature), Sterile Stop Cocks (with or without extension tube), Sterile I.V. Administration Set, Sterile Burette Set, Sterile Extension tubing / Pressure monitoring tubing, Sterile flow regulator, Sterile Blood Transfusion set.**

**Anaesthesia and Respiratory care: Sterile Endotracheal tubes, Sterile Mucus extractor, Sterile Suction Catheter, Sterile Tracheostomy tube, Sterile HME (heat and moisture exchanger) filter, Sterile Oxygen mask, Sterile Twin Oxygen set (Nasal Cannula), Sterile Nebulizer mask, Sterile Lung Exerciser, Sterile Bain Circuit, Sterile Ventilator Circuit and Sterile Catheter mount**

**Surgery & Wound Care: Sterile Yankur suction set and Sterile Chest drainage catheter**

**Urology: Sterile Foleys catheter and Sterile Nelaton / Urethral catheter.**

**Gastroenterology: Sterile Ryle's Tube and Sterile Infant Feeding Tube.**