



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 & Gastroenterology.**

This certificate is valid from 28 March 2019 until 17 July 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 March 2020
Issue 2. Certified since 17 July 2014



Authorised by

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HC SGS 13485 2016 0118

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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.

