EC Certificate Full Quality Assurance System: Certificate IN19/818843708

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

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 & Sterile Injection stopper (Needle free, Injection able using needle & with or without multi lumen extension tubes).
Urology: Sterile Foleys catheter.
Anaesthesia & Respiratory care: Sterile Endotracheal Tube (Plain & Cuffed).
Surgery & Wound Care: Sterile Yankauer Handle with Connecting Tube.

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.

This certificate is valid from 18 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 17 July 2014.

Certification is based on reports numbered IN/GUR 235605

Authorised by

Global Medical Devices Head of Notified Body

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