



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

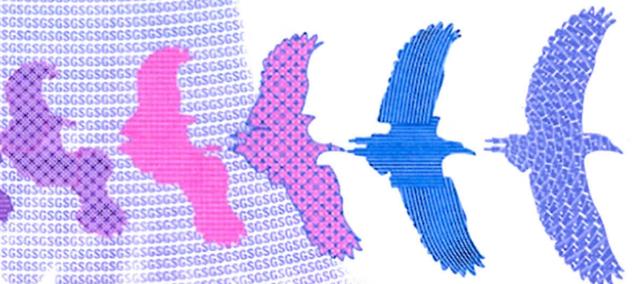


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HC SGS 13485 2016 0118

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EC Certificate Full Quality Assurance System: Certificate IN19/818843708

SGS

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. Urology: Sterile Foleys catheter**

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 27 April 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 17 July 2014 and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered IN/GUR 235605

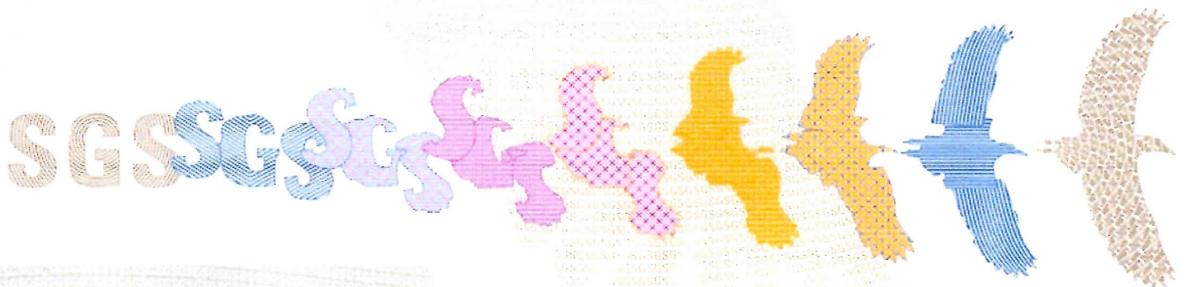
Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificato CE 1639 Annex II-4\_EN rev. 02

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## **2. Declaration of Conformity (Conformity Certificate)**

### **Manufacture**

Name: Mais India Medical Devices Pvt. Ltd.,  
525 P, Sector - 37,  
Pace City-II, Gurgaon-122001, Haryana, India,  
TEL.: + 91-124 404 7533  
FAX: +91-124 404 7533  
E-mail: [info@maisindia.com](mailto:info@maisindia.com)

### **European Union Authorized Representative**

**Name:**  
Obelis S.A.  
**Address:**  
Boulevard General Wahis 53, B-1030 Brussels, Belgium.

### **Medical Device**

S. no.	Products	UMDNS code	GMDN Code	Type of device	Duration of use		Applicable
					A	B	
1.	I.V. Cannula With Safety Features	18331	34920	Surgically Invasive Devices	A	Transient	
					B	Short Term	✓
					C	Long Term	

### **Models / Brands covered**

S. No.	Product	Brands/Models
1.	I.V. CANNULA WITH SAFETY FEATURES	<b>MAISSAFE</b>

## Technical Information of the Device

Sizes & Codes:

Size	Colour Code	Ext. Dia. mm	Catheter Length mm	Flow Rate ml./min	Product Ref. No.	Barcode (GTIN)
14G	 Orange	2.1	45	300	I107010414	8906065480257
16G	 Grey	1.7	45	200	I107010416	8906065480264
17G	 White	1.5	45	140	I107010417	8906065480271
18G	 Green	1.3	45	95	I107010418	8906065480288
20G	 Pink	1.1	32	62	I107010420	8906065480295
22G	 Blue	0.9	25	33	I107010422	8906065480301
24G	 Yellow	0.7	19	20	I107010424	8906065480318
26G	 Violet	0.6	19	15	I107010426	8906065480325

**Classification:**

This Device is used for short-term use, as per rule 7 this is classified as class IIa device as per Annex IX of Medical Devices Directive 93/42/EEC (amended by Directive 2007/47/EC)

Or

**Class B**, medical device as per part I of fourth schedule of Medical device rules G.S.R. 78 (E) 2017 according to Indian MDR.

**'B'** under serial no. 200 as per file no: 29/Misc.13/2017-DC (292), published notice 01 November 2017, according to Indian MDR 2017.

**Conformity assessment procedure:**

According to annex II (excluding section IV) of the council directive 93/42/EEC of 14<sup>th</sup> June 1993 concerning medical devices.

Or

Medical device rules G.S.R. 78(E) 2017 according to Indian MDR.

## Technical Information of the Device

### **Declaration of conformance:-**

We herewith declare that the above mentioned product (s) with CE mark meet the provision of the EC council directive 93/42/EEC of 14<sup>th</sup> June 1993 concerning medical devices.

And

Medical device rules G.S.R. 78(E) 2017

### **Referenced standard(s):**

EN ISO 13485:2016  
ISO 10555-1:2013  
ISO 10555-5:2013  
ISO 23908:2011  
EN ISO14971:2019  
ISO 11135:2014  
ISO-10993-1:2018  
ISO 10993-7:2008  
ISO 11607-1 & 2:2019  
EN ISO 15223-1:2016  
ISO 80369-7:2016  
ISO 11737-1:2018

### **Notified body:**

SGS Belgium, Notified Body 1639

Address of Notified Body: SGS House, Noorderlaan 87, 2030 Antwerp, Belgium

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F+32(0)3 545-48-49

CE certificate(s):- **IN19/818843708**

EC certificate(s) Valid until: - 24<sup>th</sup> May 2024

Person keeping the technical documentation: - Mr. Deep Singh Rawat

Date of declaration of conformity: 05/08/2022



Deep Singh Rawat  
(Manager QA & MR)  
Mais India Medical Devices Pvt. Ltd.