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

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

UKAS MANAGEMENT SYSTEMS
0005

Digitally signed by Iarovoi Petru
Date: 2020.08.20 12:11:15 EEST
Reason: MoldSign Signature
Location: Moldova

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. 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
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

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
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	**MAISSAFE**

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.l3/2017-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 14thJune 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 14th 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

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

CE certificate(s):- IN19/818843708

EC certificate(s) Valid until: - 24th 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.