EC Certificate
Full Quality Assurance System

A DNV GL COMPANY

Certificate No.:	Project No.:	Valid Until:
11305-2017-CE-IND-NA-PS Rev. 1.0	**PRJC-248537-2010-PRC-IND**	**21 October 2021**

This is to certify that the quality system of:

Madhu Instruments Pvt. Ltd.
F-90/3D, Okhla Industrial Area, Phase-1,
New Delhi – 110 020, INDIA

For design, production and final product inspection/testing of:

Sterile Disposable Medical Devices for Ophthalmology Procedures

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Digitally signed by Iarovoi Petru
Date: 2020.08.20 12:10:59 EEST
Reason: MoldSign Signature
Location: Moldova

FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. * REPUBLICA MOLDOVA
Sogno S.R.L. IDNO 1004600013854

Place and Date:
Høvik, 18 July 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Villy Rønneberg

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift om Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
0.0	Supersedes DNVGL (NB 0434) Certificate no: 8911-2016-CE-IND-NA following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-16
1.0	**EU Representative Change of Address**	**2018-07-18**

Products covered by this Certificate

Product Description	Product	Class
Ophthalmic Diagnostic Strips	Schirmer Tear Test Strips with or without Blue Mark	Im
Ophthalmic Devices for Tissue Manipulation	Cellulose Sponge Spears; PVA Sponge Spears, Silicon Tire - 276, 277, 279, 280, 281, 287; Silicon Band 2.0, 2.5, 3.0, 3.5, 4.0, 5.0mm; Silicon Sponge 3.0, 4.0, 5.0, 6.0mm	Is
Ophthalmic Devices for Tissue Manipulation	Iris Retractors; Capsular Tension Ring Size 12-10mm, 13-11mm, 14-12mm; Capsular Tension Ring with Scleral Fixation Arm Size 12-10mm, 13-11mm, 14-12mm for Left, Right, Both; Capsular Tension Ring Injector Manual loading, Self-Loading; Lens Glide; Temporary Keratoprosthesis Dia Size 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm; Scleral Plug 19g, 20G, 23G, 25G; Capsule Hook; Suction Well 8.0, 9.0, 10.0 mm; Pupil Dilator 3 to 8 loop; Capsule Support Segment; Teflon Block	IIa
Surgical Blades and Knives	Disposable Trephine 1 to 20mm; Suction Trephine 6mm to 20mm; Micro Incision Blade - Lance Tip (15^0 to 45^0), Slit (1.2 to 4.0mm), MVR (19G, 20G, 23G & 25G), Crescent, Enlarger (5.0 to 5.5mm)	IIa
Ophthalmic Cannula	Vitrectomy Infusion Cannula - 2.5mm, 4.0mm, 6.0mm; Silicon Tipped Cannula - Regular/Brush Tip (20G, 23G, 25G,27G) Regular/Brush Green Tip (20G, 23G, 25G,27G); Backflush Flute Needle with Silicon Tip Cannula 20G, 23G, 25G, 27G; Anterior Chamber Maintainer 19G, 20G; Lacrimal Intubation Set (DCR) Regular / Olive Tip (4.5, 7.5cm, 11cm, 15cm, 17.5cm); Anaesthesia 19g, 21g, 23g, 25g, 27g; Air injection & Irrigating 16g, 19g, 20g, 21g, 23g, 25g, 26g, 27g, 28g, 30g; Hydrodissection / Hydrodelineation 23g, 25g, 27g, 30g; Cortex Aspirating 21g, 23g, 25g, 26g; Irrigating & Aspirating 23/23, 22/23, 23/22; Capsule Polishers 25g, 27g; Lens Removal 23g; Vitreoretinal 20g, 23g, 25g; Bimanual 23g; Lasik 16g, 23g, 25g, 27g, Cystotome 25g, 26g, 27g, 30g	IIa

The complete list of devices is filed with the Notified Body.

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Sites covered by this certificate

Site Name	Address
Madhu Instruments Pvt. Ltd. (Unit I)	F-90/3D, Okhla Industrial Area, Phase-1, New Delhi – 110 020, INDIA
Madhu Instruments Pvt. Ltd. (Unit II)	A 260, Okhla Industrial Area, Phase-1, New Delhi – 110 020, INDIA

EU Representative: Med Devices Lifesciences Limited,
20-22 Wnlock Road
London, NI 7GU,
U.K.
Phone: +44 – 84552 80533
Email: info@meddevices.net

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

qualityaustria
Succeed with Quality

CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **quality**austria certificate to the following organisation:

Madhu Instruments Pvt. Ltd
F-90/3D,Okhla Industrial Area, Phase -1,
New Delhi – 110 020, India
Sites: A 260, Okhla Industrial Area, Phase -1,
New Delhi, 110 020, India

Manufacture, Development, Export & Supply of Disposable and reusable Medical Devices for Surgical, Diagnostic and Training of ophthalmic Procedures

The validity of the **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

This **quality**austria certificate confirms the application and further development of an effective

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

Registration No.: 00154/0
Date of initial issue: 25 March 2014
Valid until: 31 March 2021

qualityaustria

IQNet

Vienna, 30 April 2018

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
General Manager

Ing. Andreas Aichinger, MSc
Specialist representative

Sogno S.R.L. IDNO: 1004600013854 REPUBLICA MOLDOVA MUN. CHIŞINĂU

65a24847-26c5-4125-9975-d849aae7ba29

The current validity of the certificate is documented exclusively on the Internet under http://www.qualityaustria.com/en/cert EAC: 19.2