EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 11305-2017-CE-IND-NA-PS Rev 4.0

Initial certification date: 16 October 2017

Valid Until: 27 May 2024

This is to certify that the quality system of:

Madhu Instruments Pvt. Ltd.

A - 260, 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

Digitally signed by Iarovoi Petru
Date: 2021.10.07 16:03:50 EEST
Reason: MoldSign Signature
Location: Moldova

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

Place and date:
Høvik, 18 May 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Alessandra Rinna
Assessor

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)	16 Oct 2017
1.0	EU Representative Change of Address	18 Jul 2018
2.0	EU Representative Change	10 Feb 2020
3.0	Recertification	13 May 2021
4.0	Editorial changes	18 May 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Ophthalmic Diagnostic Strips	MIPL/A1 Schirmer Tear Test Strips Brand: Tear Touch MIPL/A6 Schirmer Tear Test Strips with Blue Mark Brand: Tear Touch Blue	Im /Is
Ophthalmic Devices for Tissue Manipulation	MIPL/B1 Cellulose Sponge Spears Brand : High Soak MIPL/B2 PVA Sponge Spears Brand : Soft Soak	Is

Ophthalmic Devices for Tissue Manipulation	MIPL/D1 Iris Retractors Brand: Iris Care MIPL/D2 Capsular Tension Ring Size 12-10mm, 13-11mm, 14-12mm MIPL/D3 Capsular Tension Ring with Scleral Fixation Arm Size 12-10mm, 13-11mm, 14-12mm (for Left, Right, Both) MIPL/D4 Capsular Tension Ring Injector MIPL/D8 Capsule Hook Brand : Capsule Care MIPL/D10 Pupil Dilator 3 to 8 loop Brand : Gupta Ring MIPL/D11 Capsule Support Segment Brand : Gupta Segment	IIa
Surgical Blades and Knives	MIPL/C1 Corneal Trephine - 1 to 20mm Brand: Nano Edge MIPL/C2 Suction Trephine - 6mm to 20mm Brand: Nano Edge MIPL/C4 Trephine Punch (vacuum & non-Vacuum) 6mm to 20mm Brand: Nano Edge MIPL/C3 Micro Incision Blade – a. Lance Tip (15^0 to 45^0) Brand: Nano Edge b. Slit (1.2 to 4.0mm) Brand: Nano Edge c. MVR (19G, 20G, 23G & 25G) Brand: Nano Edge d. Crescent (1 to 2.5 mm) Brand: Nano Edge e. Enlarger (5.0 to 5.5mm) Brand: Nano Edge	IIa

Ophthalmic Cannula	MIPL/E2 Silicon Tip Cannula - Regular/Brush Tip (20G, 23G, 25G,27G) MIPL/E4 Anterior Chamber Maintainer 19G, 20G,23G MIPL /E5 Lacrimal Cannula (DCR) Regular / Olive Tip (4.5, 7.5cm, 11cm, 15cm, 17.5cm) MIPL/E6 Anaesthesia Cannula 19G,21G, 23G, 25G, 27G MIPL/E7 Cystotome Cannula 25G, 26G 27G, 30G MIPL /E8 Air injection & Irrigation Cannula 16G ,19G ,20G,21G,23G ,25G ,26G ,27G, 28G,30G MIPL /E9 Hydrodissection / Hydrodelineation Cannula 23G, 25G, 27G, 30G MIPL /E10 Cortex Aspirating Cannula 21G, 23G, 25G, 26G MIPL /E11 Irrigating & Aspirating Cannula 23/23,22/23, 23/22 MIPL /E12 Capsule Polishers 21G,23G,25G,27G MIPL /E15 Bimanual Cannula 21G,22G,23G MIPL /E16 Lasik Cannula 16G, 23G, 25G, 27G Brand: Maxiflo (All cannulas)	IIa
Cataract Protection	MIPL/O3 Eye Shield Brand : Clear Shield	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Madhu Instruments Pvt. Ltd. (Unit II)	A - 260, Okhla Industrial Area, Phase-1, New

	Delhi – 110 020, INDIA

EU Representative

Obelis s.a. Bd , General Wahis 53, B-1030 Brussels , Belgium

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. the Notified Body 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.

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

incl. site: A 260, Okhla Industrial Area,
Phase -1, New Delhi, 110 020, India

Development, Manufacture and Supply of Diagnostic & Surgical devices used in ophthalmology like Ophthalmic Diagnostic Strips, Ophthalmic Devices for Tissue Manipulation, Surgical Blades & Knives, Ophthalmic Cannula, Ophthalmic Microsurgery Instruments, Silicon Device(Silicon Band, Silicon Sponge, & Silicon Tire), Diagnostic & Surgical Lenses, Ophthalmic Devices for Teaching & Training Devices, Ophthalmic Surgical Instruments, Cataract Protection.

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 2024

Vienna, 30 March 2021

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

Konrad Scheiber
General Manager

Dr. Mag. Anni Koubek
Specialist representative

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy)

Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture Forestry, Environment and Water Management)

Quality Austria is authorized by the VDA (Association of the Automotive Industry)

For accreditation registration details please refer to the applicable decisions or recognition documents

Quality Austria is the Austrian member of IQNet (International Certification Network)

Dok. Nr. FO_24_028

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