



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

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

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

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

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

<p>Ophthalmic Devices for Tissue Manipulation</p>	<p>MIPL/D1 Iris Retractors Brand: Iris Care</p> <p>MIPL/D2 Capsular Tension Ring Size 12-10mm, 13-11mm, 14-12mm</p> <p>MIPL/D3 Capsular Tension Ring with Scleral Fixation Arm Size 12-10mm, 13-11mm, 14-12mm (for Left, Right, Both)</p> <p>MIPL/D4 Capsular Tension Ring Injector</p> <p>MIPL/D8 Capsule Hook Brand : Capsule Care</p> <p>MIPL/D10 Pupil Dilator 3 to 8 loop Brand : Gupta Ring</p> <p>MIPL/D11 Capsule Support Segment Brand : Gupta Segment</p>	<p>Ila</p>
<p>Surgical Blades and Knives</p>	<p>MIPL/C1 Corneal Trephine - 1 to 20mm Brand: Nano Edge</p> <p>MIPL/C2 Suction Trephine - 6mm to 20mm Brand: Nano Edge</p> <p>MIPL/C4 Trephine Punch (vacuum & non-Vacuum) 6mm to 20mm Brand: Nano Edge</p> <p>MIPL/C3 Micro Incision Blade –</p> <ol style="list-style-type: none"> Lance Tip (15° to 45°) Brand: Nano Edge Slit (1.2 to 4.0mm) Brand: Nano Edge MVR (19G, 20G, 23G & 25G) Brand: Nano Edge Crescent (1 to 2.5 mm) Brand: Nano Edge Enlarger (5.0 to 5.5mm) Brand: Nano Edge 	<p>Ila</p>

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



Certificate No.: 11305-2017-CE-IND-NA-PS Rev 4.0
Place and date: Høvik, 18 May 2021

	Delhi – 110 020, INDIA
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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