EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid until:
217514-2017-CE-IND-NA-PS 0.0	PRJC-495266-2013-MSL-IND	12 JUNE 2022

This is to certify that the quality system of:

Moss Vision Incorporation Ltd
120 Viglen House, Alperton Lane, Wembley, Middlesex, HA0 1HD, United Kingdom

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

Intra Ocular Lens, Accessories & Solutions for ophthalmic use

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) 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, 2017-06-29

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus

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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Certificate No.: 217514-2017-CE-IND-NA-PS 0.0
Project No.: PRJC-495266-2013-MSL-IND
Valid until: 12 JUNE 2022

Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate (Supercedes certificate no. 3878-2007-CE-NOR for notification change from NB 0434 to NB 2460)	2017-06-29

Products covered by this Certificate:

Product Description	Product Name	Class
Intra ocular lenses	• Optiflex PMMA Intra Ocular Lens • Single piece Intra Ocular Lens with optic diameter between 5.0-7.0 mm and overall diameter between 12-13.5 mm Models: MO/P-006, MO/P-AC01, MO/P-003	IIb
Intra ocular lenses	• Optiflex Hydrophilic Acrylic Foldable Intra Ocular lens Models: MO/F-001, MO/F-002, MO/F-003, MO/F-006	IIb
Intra ocular lenses	• Optiflex Hydrophobic Surface Acrylic Foldable Intra Ocular lens Models: MO/F-013, MO/F-014, MO/FNYA-01, MO/FNYA-03	IIb
Intra ocular lenses	• Optiflex Clear Hydrophobic Foldable Intra Ocular lens Models: MO/F-022	IIb
Intra ocular lenses	• Optiflex Yellow Hydrophobic Foldable Intra Ocular lens Models: MO/HF-011, MO/HF-012, MO/F-023, MO/HF-D012	IIb
Intra ocular lenses	• Optiflex Toric Aspheric Hydrophobic	IIb

	Acrylic Foldable Intra Ocular Lens Models: MO/HFY-013	
Intra ocular lenses	• Optiflex Phakic Aspheric Hydrophilic Acrylic Foldable Intra Ocular Lens Models: MO/F-MZ015, MO/F-MZ018, MO/F-MZ020	IIb
Accessories:	• Optiflex Injector Models: OFIHL, OFIMC • Optiflex Injector Cartridge Models: OFC 150, OFC 145, OFC 180	IIa
Sodium Hyaluronate Ophthalmic solutions	• Optiflex Sodium Hyaluronate Ophthalmic Solutions 10 mg/ml Quantity: 1.0 ml • Optiflex Sodium Hyaluronate Ophthalmic Solutions 14 mg/ml Quantity: 1.0 ml • Optiflex Sodium Hyaluronate Ophthalmic Solutions 18 mg/ml Quantity: 1.0 ml • Optiflex Sodium Hyaluronate Ophthalmic Solutions 24 mg/ml Quantity: 1.0 ml • Optiflex Combipack- Sodium Hyaluronate Ophthalmic Solutions in PFS • Optiflex Sodium Hyaluronate Ophthalmic Solutions 30 mg/ml Quantity: 1 ml PFS	IIb
Hydroxy Propyl Methyl Cellulose Ophthalmic Solution	• Optiflex 2 ml PFS • Optiflex 2 ml Plus PFS	IIb
Silicone Oil 1000 cst	• Optisol Silicon oil 1000 cst 10ml vial and PFS	IIb
Silicone Oil 5000 cst	• Optisol Silicon oil 5000 cst 10ml vial and PFS	IIb
Perfluoro-n-Octane Liquid	• Optisol-Perfluoro-n-Octane sterile liquid 5 ml and 7 ml vial and PFS	IIb

Perfluorodecalin Liquid	• Optisol Perfluorodecalin sterile liquid 5 ml and 7 ml vial and PFS	IIb
Trypan Blue Ophthalmic Solution (0.06 % w/v)	• Opti Blue PFS 1ml PFS or pack of 5 or 10 PFS	IIb
Brilliant Blue G or Acid Blue 90 Ophthalmic Solution (0.25 mg/ml)	• Opti Blue G 0.5 ml or 1 ml PFS	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Moss Vision Incorporation Ltd, 120 Viglen House, Alperton Lane, Wembley, Middlesex, HA0 1HD, United Kingdom

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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