EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
243634-2017-CE-IND-NA-PS Rev. 0.0	PRJC-529150-2015-MSL-IND	14 July 2022

This is to certify that the quality system of:

OPHTECHNICS UNLIMITED
2209, Phase IV, DLF City,
Gurgaon – 122 002,
Haryana, India.

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

Ophthalmic Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) 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, 14 July 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård

Bjørg Synnøve Nesgård

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

Digitally signed by Chirtoacă Iurie
Date: 2021.10.08 14:00:46 EEST
Reason: MoldSign Signature
Location: Moldova

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

EC Certificate
Full Quality Assurance System

Certificate No.: 243634-2017-CE-IND-NA-PS Rev. 0.0
Project No.: PRJC-529150-2015-MSL-IND
Valid Until: 14 July 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	2017-07-14

Products covered by this Certificate:

Product Description	Product Name	Class
Ophthalmic Strips		
Fluorescein Sodium Ophthalmic Strip	0.6mg and 1.0mg per Strip	Is
Schirmer Tear Test Strips	Plain & Blue Band	Im
Ophthalmic Solutions		
Sodium Hyaluronate solution in vial or prefilled syringe	1%, 1.4%, 1.8%, 2.4%	IIb
Hydroxypropyl Methyl Cellulose Ophthalmic Solution	2%, 2.5%	IIb
Trypan Blue Ophthalmic Solution	0.6 mg/ml, 0.8mg.ml, 1.5 mg/ml	IIb
Silicone Oil Ophthalmic Solution	1000cst, 1200cst, 2000cst, 5000cst	IIb
Carboxymethyl Cellulose Sodium Lubricant Eye Drop	0.5%, 1%	IIb
Hydroxypropyl Methyl Cellulose Lubricant Eye Drop	0.3%, 0.5%	IIb
Polyethylene Glycol 400 & Propylene Glycol Lubricant Eye Drop	PEG 400 NF 0.4%w/v & PG 0.3%w/v	IIb
Sodium Hyaluronate Lubricant Eye Drop	0.1%, 0.15%, 0.3%	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

EC Certificate
Full Quality Assurance System

Certificate No.: 243634-2017-CE-IND-NA-PS Rev. 0.0
Project No.: PRJC-529150-2015-MSL-IND
Valid Until: 14 July 2022

Site Name	Address	Site Scope
OPHTECHNICS UNLIMITED	2209, Phase IV, DLF City, Gurgaon – 122 002, Haryana, India.	Production and final product inspection/testing of Ophthalmic Medical Devices

EU Representative

Advena Ltd., Pure Offices, Plato Close, Warwick CV34 6WE, U.K.

Telephone: +44 (0)1926800153, email: info@advenamedical.com

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
243634-2017-CE-IND-NA-PS Rev. 0.0	PRJC-529150-2015-MSL-IND	14 July 2022

This is to certify that the quality system of:

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Ophthalmic Devices

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Place and Date:
Høvik, 14 July 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård

Bjørg Synnøve Nesgård

The Certificate has been digitally signed.
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EC Certificate
Full Quality Assurance System

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Project No.: PRJC-529150-2015-MSL-IND
Valid Until: 14 July 2022

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Sites covered by this certificate

EC Certificate
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