DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 52925-2009-CE-IND-NA Rev. 3.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Action Medical Marketing Pvt. Ltd.

Works : Gat No 528, Koregaon Bhima, Pune-Nagar Highway,
Taluka: Shirur, Dist: Pune, Pin 412216, INDIA.

for design, production and final product inspection/testing of

Intraocular Lenses and Devices for Intraocular Surgery

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 are given overleaf

Place and date:
Høvik, 09 May 2016

For DNV GL BUSINESS ASSURANCE
NORWAY AS

Tone Kolpus

Tone Kolpus
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

Digitally signed by Iarovoi Petru
Date: 2019.12.13 15:28:51 EET
Reason: MoldSign Signature
Location: Moldova

CE

Notified Body No.:
0434

This Certificate is valid until:
09 Ma[illegible]

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info.

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300,000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.

Presafe®
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
248860-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-522654-2015-MSL-IND**	**09 May 2021**

This is to certify that the quality system of:

Action Medical Mktg Pvt Ltd.
Works : Gat No 528, Koregaon Bhima, Pune-Nagar Highway,
Taluka: Shirur, Dist: Pune, Pin 412216, INDIA.

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

Intraocular Lenses and Devices for Intraocular Surgery

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, 7 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

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.

EC Certificate
Full Quality Assurance System

Certificate No.: **248860-2017-CE-IND-NA-PS Rev. 0.0**
Project No.: **PRJC-522654-2015-MSL-IND**
Valid Until: **09 May 2021**

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: 52925-2009-CE-IND-NA Rev. 3.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-11-07

Products covered by this Certificate:

Product Description	Product Name	Class
Intraocular Lens	▪ PMMA Intraocular Lenses • Envision Brand (Models: EN120500, EN120525, EN125550, EN125600, EN125602, EN125650, EN125652, EN130600, EN130602, EN130650, EN130652, EN135562, EN135652, EN-AC125, EN125602SQ, EN120525SQ) • 3D Brand (Models: 3D120500, 3D120525, 3D125550, 3D125600, 3D125602, 3D125650, 3D125652, 3D130600, 3D130602, 3D130650, 3D130652, 3D135562, 3D135652, 3D-AC125, 3D125602SQ, 3D120525SQ) In addition, all models with any combination of optic size from 5,00 to 7,00 mm and diameter from 12,00 to 14,00 mm with or without holes. ▪ FOLDABLE Hydrophillic Intraocular Lenses • Hydrophilex Brand (Models: HF125575, HF120575SQ, HF125600, HF125600SQ, HF110600QD, HF-125600TR, HF125600DF, HF-HDPH-DF, HF-HDPH-TR, Toric IOLs, Multifocal IOLs • UFold Brand (Models: UF125575, UF120575SQ, UF125600, UF125600SQ, UF110600QD , UF-	IIb

	125600TR, UF125600DF, UF-HDPH-DF, UF-HDPH-TR), Toric IOLs, Multifocal IOLs) In addition, all models with optic size from 5,00 to 7,00 mm and diameter size from 11,00 to 13,00 mm with and without delivery systems. ▪ FOLDABLE Hydrophobic Intraocular Lenses. ActionFold Brand (Model: AF-125600-PBA, AF-125600TR, AF125600DF, AF-HDPH-DF, AF-HDPH-TR) with and without delivery systems. Toric IOLs, Multifocal IOLs) with and without delivery systems.	
Ophthalmic Implant	▪ Capsular Tension Rings (CTR): Brand C-Tring (Models AMTR-10, AMTR-11, AMTR-12)	IIb
Devices for Ophthalmic Surgery	▪ Injectors: Brand Hydro-Fold (Models IM50185) ▪ Cartridges: Brand Hydro-Fold (Models IM50184, IM50184S, IM50184M)	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Action Medical Mktg Pvt Ltd.	Gat No 528, Koregaon Bhima, Pune-Nagar Highway, Taluka: Shirur, Dist: Pune, Pin 412216, INDIA.

EU Representative

Obelis, S.A, Bd General Wahis 53, B1030 Brussels, Belgium

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
248860-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-522654-2015-MSL-IND**	**09 May 2021**

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

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
248846-2017-AQ-IND-NA-PS Rev. 3.0	**PRJC-522654-2015-MSL-IND**	**06 MAY 2009**	**06 MAY 2021**

This is to certify that the management system of:

Action Medical Mktg Pvt Ltd.

Gat No. 528, Pune – Nagar Highway, Koregoan Bhima, Taluka: Shirur, Dist.: Pune, Pin 412 216, India

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, Manufacturing, Marketing and Supply of sterile / Nonsterile single use Intraocular Lenses, Capsular Tension Rings, Devices for Ophthalmic and ENT surgery like injectors, cartridges, surgical disposables, sterile / non-sterile microsurgical instruments, Cataract Blades, Surgical Procedure Kits and Ophthalmic Solutions

Place and Date:
Høvik, 14 June 2019

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Elise Kolpus

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