EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 248860-2017-CE-IND-NA-PS Rev. 2.0 Project No.: PRJC-522654-2015-MSL-IND Valid Until: 27 May 2024

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 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 15:28:13 EEST
Reason: MoldSign Signature
Location: Moldova

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

Place and date:
Høvik, 15 May 2021

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

Palani Damodharan
Principal 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: 52925-2009-CE-IND-NA Rev. 3.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	07 November 2017
1.0	Re-issuing the certificate with QR Code	08 July 2020
2.0	Recertification	15 May 2021

Products covered by this Certificate:

Product Description	Product Name	Class
PMMA Intraocular Lenses	Envision Brand: (Models: EN120500, EN120525, EN125550, EN125600, EN125602, EN125652, EN130600, EN130602, EN130650, EN130652, EN135652, EN-AC125, EN125602SQ, EN120525SQ, EN135650) 3D Brand: (Models: 3D120500, 3D120525, 3D125550, 3D125600, 3D125602, 3D125652, 3D130600, 3D130602, 3D130650, 3D130652, 3D135652, 3D-AC125, 3D125602SQ, 3D120525SQ, 3D135650)	IIb
Hydrophilic Foldable Intraocular Lenses	UFOLD Brand: UF125600, UF125600SQ, UF110600QD, UF1TORQT*, UF1DIFQ, UF1DIFF, UF1TORCT*, UF1TRIQ), Toric IOLs, Multifocal IOLs (* has cylinder value from 1 to 9) Hydrophilex Brand (Models: HF125600, HF125600SQ, HF110600QD, HF1TORQT*, HF1DIFQ, HF1DIFF, HF1TORCT*, HF1TRIQ,	IIb

	Toric IOLs, Multifocal IOLs (* has cylinder value from 1 to 9) UFold / Hydrophilex hydrophilic IOLs with or without delivery systems. 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.	
Hydrophobic Foldable Intraocular Lenses	ActionFold Brand: AF-125600-PBA, AF-125600-PBAY, AF1TORQT*, AF1DIFFY) with and without delivery systems. (Toric IOLs, Multifocal IOLs) with and without delivery systems. (* has cylinder value from 1 to 9) ActionFold Hydrophobic IOLs can also be supplied as Preloaded IOLs also. 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.	IIb
Lens Delivery Systems	Injectors: Brand Hydro-Fold (Models IM50185) Cartridges: Brand Hydro-Fold (Models IM50184, IM50184S, IM50184M)	IIa
Cataract Blades	PrecisionCut brand Cataract Blades in following variants • Slit / Keratome Knives (Sharp Tip & Blunt Tip) Angulation 45 Deg. Bevel Up/Bevel Down/Straight • Tunnel Pocket /Crescent Knives in Angulation 45 Deg. Bevel Up/Bevel Down/Straight • Lance Tip/Side Port/Stab Knives Straight / Angle Left/Angle Right • Clear Corneal Knives Angulation 45 Deg. Bevel Up/Bevel Down/Straight • MVR Knives Angulation 45 Deg. /Straight	IIa

	All blades can be supplied in all possible variants of tip sizes	

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

MED DEVICES LIFESCIENCES B. V. Kraijenhoffstraat 137 A, 1018RG Amsterdam, the Netherlands

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

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Action Medical Mktg Pvt. Ltd.

Gat No 528, Koregaon Bhima,Pune Nagar Rd, Tal Shirur, Dist. Pune - 412216, Maharashtra, India

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

Organization was certified by another Certification Body before 04/05/2021.

The management system is applicable to:

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.

Certificate Number:
0115238

Initial Certification Date:
06 May 2009

Date of Certification Decision:
27June 2021

Issuing Date:
29 June 2021

Valid Until:
05 May 2024

ISO 13485:2016 CERTIFICATION ™
Intertek

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Calin Moldovean
President, Business Assurance

Intertek India Private Limited, F-Wing, 2nd Floor, Tex Centre, Chandivali Farm Road, Andheri (East), Mumbai - 400 072, India