

EC CERTIFICATE

Number: 49290CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

Ophtec B.V.

Schweitzerlaan 15
9728 NR Groningen
The Netherlands

For the product category(ies)

Intraocular devices and accessories

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 49290CN, initially dated 1 February 1995
Addendum, initially dated 1 February 2001

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 July 2023
Issued for the first time: 1 February 1995
Reissued: 1 July 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 49290CE01

1/2

CE MARKING OF CONFORMITY MEDICAL DEVICES

Intraocular devices and accessories

Issued to:

Ophtec B.V.
Schweitzerlaan 15
9728 NR Groningen
The Netherlands

This certificate covers the following product(s): (Class IIb)

PMMA intraocular lenses (Class IIb):

- Artisan Phakic / Verisyse Phakic
- Artisan Aphakia / Verisyse Aphakia
- Artisan Toric / Verisyse Toric
- Aniridia Intraocular Lenses

PMMA Tension Rings (Class IIb):

- Capsular Tension Rings / StabilEyes
- Iris Prosthetic System

PMMA Preloaded Tension Rings (Class IIb):

- RingJect

Silicone intraocular devices (Class IIb):

- Artiflex Myopia / VeriFlex Myopia
- Artiflex Toric

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A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 49290CE01

2/2

CE MARKING OF CONFORMITY MEDICAL DEVICES

Intraocular devices and accessories

Issued to:

Ophtec B.V.
Schweitzerlaan 15
9728 NR Groningen
The Netherlands

Hydrophilic acrylic intraocular devices (Class IIb):

- ErgomaX
- MonomaX
- QuadrimaX
- Precizon Monofocal
- Precizon Toric
- Precizon Presbyopic
- Precizon Presbyopic NVA

Initial date: 1 February 2001

Revision date: 1 July 2018

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drs. G.J. Zoetbrood
Managing Director

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