EC CERTIFICATE

Number: 2117207CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Oculentis B.V.

Kollergang 9
6961 LZ Eerbeek
The Netherlands

For the product category(ies)

Sterile Intraocular Lenses

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 2117207CN, initially dated 6 April 2009
Addendum, initially dated 3 June 2008

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, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II 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: 3 June 2008
Reissued: 1 July 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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
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ADDENDUM

Belonging to certificate: 2117207CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile Intraocular Lenses

Issued to:

Oculentis B.V.
Kollergang 9
6961 LZ Eerbeek
The Netherlands

This certificate covers the following product(s):

Class IIb:
- Multi Piece Acrylic IOL
- Single Piece Acrylic IOL

Class IIa and Class III:
- Viscoelastic Solutions

Class IIa and Class IIb
- Vitreoretinal Products

Class Is
- Capsulotomy Lenses

Initial date: 3 June 2008
Revision date: 1 July 2018

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