EC CERTIFICATE

Number: 2085692CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.

Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

For the product category(ies)

Ophthalmic Surgical Instruments, Systems, Equipment

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 93929CN, initially dated 2 September 1999
Addendum, initially dated 7 June 2009

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: 26 May 2024
Issued for the first time: 19 June 2006
Reissued: 21 February 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2085692CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Ophthalmic Surgical Instruments, Systems, Equipment

Issued to:

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

This certificate covers the following product(s):

Class IIb active devices:
- Phacoemulsification/vitrectomy system

Class IIa active devices:
- Vitrectomy system generator

Class IIa devices:
- Ophthalmic scissors, probe-like, single-use
- Ophthalmic soft-tissue surgical manipulation forceps, probe-like, single-use
- Intraocular retractor, single-use
- Vitrectomy fluid/gas handling handpiece/cannula
- Ophthalmic infusion/aspiration cannula, non-illuminating, reusable
- Intraocular hook/spatula/manipulator, reusable
- Ophthalmic knife, single-use
- Epiretinal/inner limiting membrane scraper, single-use
- Scleral plug, single-use
- Ophthalmic surgical instrument handle, pneumatic
- Phacoemulsification system handpiece
- Therapeutic contact lens
- Ophthalmic cannulation set, reusable
- Ophthalmic cannulation set, single-use

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 2085692CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Ophthalmic Surgical Instruments, Systems, Equipment and Accessories

Issued to:

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

- Ophthalmic infusion/aspiration cannula, illuminating, single-use
- Ultrasonic surgical system tubing set
- Ophthalmic surgical procedure kit, non-medicated, single-use
- Ophthalmic fibreoptic-light instrument, single-use
- Ophthalmic cryosurgical system, electronic
- Phacoemulsification system handpiece tip, single-use
- Open-surgery electrosurgical handpiece – electrode, bipolar, reusable
- Ophthalmic laser system beam guide
- Donor cornea delivery set
- Ophthalmic infusion/aspiration cannula, non-illuminating, single-use

Initial date: 7 June 2009
Revision date: 21 February 2020

DEKRA Certification B.V.

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