EC CERTIFICATE

Number: 2085692CE10

Full Quality Assurance System

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

Manufacturer:

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

Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

For the product category(ies)

Opthalmic Surgical Instruments

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 February 2020

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, 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.
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: 20 July 2017
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
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ADDENDUM

Belonging to certificate: 2085692CE10

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Opththalmic Surgical Instruments

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):

Vitrectomy contact lens, single-use
System accessories

Initial date: 21 February 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

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