

# EC CERTIFICATE

Number: 2085692CE01

## 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)

### Ocular Endotamponades

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

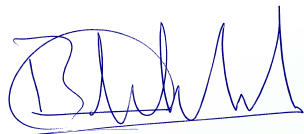
Documents, that form the basis of this certificate:

**Certification Notice 93929CN, initially dated 2 September 1999**  
**Addendum, initially dated 9 March 2011**

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

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

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# ADDENDUM

Belonging to certificate: 2085692CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Ocular Endotamponades

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

Vitreous-humour replacement medium, postoperative:

- Silicone Oil
- Ocular Gasses

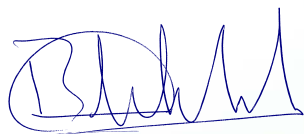
Class IIa

Vitreous/aqueous humour replacement medium, intraoperative

Initial date: 9 March 2011

Revision date: 21 February 2020

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt  
Certification Manager

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