

EC CERTIFICATE

Number: 2124770CE02

Full Quality Assurance System

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

Manufacturer:

Johnson & Johnson Surgical Vision, Inc.

1700 East St. Andrew Pl.,
Santa Ana, California, 92705,
United States

For the product category(ies)

Glaucoma Baerveldt Silicone Implant Devices

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 2124770CN, initially dated 1 November 2009
Addendum, initially dated 22 March 2010

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 November 2023
Issued for the first time: 1 November 2009
Revised: 24 May 2018
Reissued: 1 November 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ir. H. van der Woord
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: 2124770CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Glaucoma Baerveldt Silicone Implant Devices

Issued to:

Johnson & Johnson Surgical Vision, Inc.
1700 East St. Andrew Pl.,
Santa Ana, California, 92705,
United States

This certificate covers the following product(s):

BG103-250 (Class IIb)
BG101-350 (Class IIb)
BG102-350 (Class IIb)

Initial date: 22 March 2010
Revision date: 24 May 2018

DEKRA Certification B.V.

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 ir. H. van der Woord, written in a cursive style.

ir. H. van der Woord
Certification Manager

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