

EC CERTIFICATE

Number: 3811236CE02

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:

Oscor Incorporated

3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

For the product category(ies)

Medical Devices for the area of cardiological application

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 3811236CN, initially dated 7 December 2013
Addendum, initially dated 16 December 2014

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: 8 January 2020
Issued for the first time: 16 December 2014
Reissued: 18 May 2017

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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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: 3811236CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical Devices for the area of cardiological application

Issued to:

Oscor Incorporated

3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

This certificate covers the following product(s):

- Transseptal Guidewires (Class III)
- Temporary Pacemaker Leads (Class III)
- Steerable guiding sheath (Class III)
- Delivery sheaths (Class III)
- Introducer sets
 - Peelaway Introducer Sets (Class IIa)
 - Non Peelaway Introducer Sets (Class IIa)
 - Adelante Magnum (Class III)
- Guidewires (Class IIa)
- Extension Cables (Class IIa)
- Plugs (Class Is)

Initial date: 16 December 2014

Revision date: 18 May 2017

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 ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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