EC CERTIFICATE

Number: 2181711CE01

Full Quality Assurance System

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

Manufacturer:

Bioptimal International PTE. LTD.

36 Jalan Tukang
619266 Singapore
Singapore

For the product category(ies)

Critical Care Products used in intensive care units, critical care units, percutaneous interventional environments, operating theatres and nursing departments

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 2181711CN, initially dated 15 July 2015
Addendum, initially dated 11 December 2015

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: 15 July 2015
Reissued and Revised: 30 March 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: 2181711CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Critical Care Products used in intensive care units, critical care units, percutaneous interventional environments, operating theatres and nursing departments

Issued to:

Bioptimal International PTE. LTD.
36 Jalan Tukang
619266 Singapore
Singapore

This certificate covers the following product(s):

- Angiographic Kit – Class IIa
- Pressure Monitoring Systems and Kits – Class IIa
  - Accutrans
  - Catrans
  - Biotrans
- Embolectomy Catheter – Class IIa
- Central Venous Catheter and Catheterization Kit – Class III
- Bipolar Pacing Catheter – Class III
- Thermodilution Catheter and Kits – Class III
- Pulmonary Artery Monitoring Catheter and Kits – Class III
- Vascular Introducer Kit – Class IIa

Initial date: 11 December 2015

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