EC CERTIFICATE

Digitally signed by Jighili Tatiana
Date: 2023.10.16 10:41:55 EEST
Reason: MoldSign Signature
Location: Moldova

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

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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
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

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

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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CERTIFICATE

Number: 2223522

The management system of:

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

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:
Design, manufacture and distribution of Thermodilution, Pulmonary Artery, Central Venous, Embolectomy devices and Bipolar Pacing Catheters, Pressure Monitoring Systems. Assembly and distribution of Angiographic Kits and Surgical Procedure Set for Catheter Introduction. Including purchase and resale of accessories for critical care products

Certificate expiry date: 14 January 2025
Certificate effective date: 14 January 2022
Certified since: 28 January 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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MGMT. SYS. RvA C 589

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

Manufacturer's Name:	**Bioptimal International Pte. Ltd.**
	36 Jalan Tukang, #02-02 SINGAPORE 619266
Telephone / Fax:	+65 6213 5777 / +65 6213 5737
Email:	ra-bpi@bioptimalg.com
Website:	www.bioptimalg.com
Single Registration Number:	SG-MF-000010306
European Representative:	**Shanghai International Holding Corp. GmbH (Europe)**
	Eiffestrasse 80, 20537 Hamburg, GERMANY
Telephone / Fax:	+49 40 2513175 / +49 40 255726
Email:	shholding@hotmail.com
Single Registration Number:	DE-AR-000000001
Device Name:	**Thermodilution Catheter and Kits**
Brand or Trade Name:	Bioptimal Thermodilution Catheter and Biotray
Device Models & References:	Refer to Annex 1 and 2
Basic UDI-DI:	888648350900RV
Risk Classification:	**Class III, Rule 7 of Annex IX, MDD 93/42/EEC**
Conformity Assessment:	Annex II, MDD 93/42/EEC
Common Specifications Used:	Refer to ST-0049 Standard List
Intended Use:	Intended to measure cardiac output, right atrium, pulmonary artery and pulmonary capillary wedge pressures. Continuously monitor pulmonary artery temperature, sample blood, intravenously administer drugs and solution and measure cardiac output via the cardiac output computers.

We hereby declare under our sole responsibility as a manufacturer that the medical device stated herein, as manufactured by Bioptimal International Pte. Ltd., meets the requirements of EU MDD 93/42/EEC on medical devices including the amendments of the Medical Device Directive 2007/47/EC, and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment. All supporting documentation is retained at the premises of Bioptimal International Pte. Ltd.

Notified Body:	**DEKRA Certification B.V**
	Meander 1051, 6825 MJ Arnhem, The NETHERLANDS
Notified Body Number:	0344
EC Certificate No.:	2181711CE01
CE Marking under DEKRA:	First issued on 15 July 2015, reissued, and revised on 30 March 2020 with validity until 26 May 2024
EC Design Certificate No.:	2181711DE02
EC Design Certificate issued:	First issued on 15 July 2015, reissued, and revised on 01 April 2020 with validity until 26 May 2024

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Thermodilution Catheter

First lot release date: 26 November 2015
First lot number: H151000017

Biotray

First lot release date: 18 Jan 2016
First lot number: H151100222

Signature / Date: 06 Feb 2023

BIOPTIMAL INTERNATIONAL PTE. LTD.

Francis Joey Eduave
Person Responsible for Regulatory Compliance (PRRC)
On behalf of Bioptimal International Pte. Ltd.

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Annex 1

Thermodilution Catheter – Model references

Thermodilution Catheter Generic Model reference	
TD1504 TD1504-110 TD1604 TD1704 TD1755	Polyvinylchloride tubing
TD2504 TD2504-110 TD2604 TD2704 TD2755	Polyurethane tubing

Optional Features	Suffix
Safetywedge™	D
Contamination Sleeve	X
Non-coated tubing	N
Soft Body Tubing	S
Stiff Body Tubing	F
Zebra Numerical Print	Z
S-Tip Guide	C
Medication port	AV
Proximal port	M
Proximal port	G
Pacing extension	P
Longer thermistor extension (550mm)	R
Longer thermistor extension (400mm)	W
Rubber Boot	B

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Annex 2

Biotray – Model references

Biotray Generic Model reference	
BIOTRAY TD1504 BIOTRAY TD1504-110 BIOTRAY TD1604 BIOTRAY TD1704 BIOTRAY TD1755 BIOTRAY TD2504 BIOTRAY TD2504-110 BIOTRAY TD2604 BIOTRAY TD2704 BIOTRAY TD2755	Biotray with Thermodilution Catheter

Optional Features	Suffix
Safetywedge™	D
Contamination Sleeve	X
Non-coated tubing	N
Soft Body Tubing	S
Stiff Body Tubing	F
Zebra Numerical Print	Z
S-Tip Guide	C
Medication port	AV
Proximal port	M
Proximal port	G
Pacing extension	P
Longer thermistor extension (550mm)	R
Longer thermistor extension (400mm)	W
Rubber Boot	B

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Bioptimal™

LETTER OF AUTHORIZATION

Date: September 28th, 2023

To Whom It May Concern:

Hereby, we

Company Name: Bioptimal International Pte. Ltd.
Address: 36 Jalan Tukang Singapore, 619266

Certify that:

Triumf Motiv SRL
Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1
Phone number: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand [Bioptimal International] in your country.

This letter of authorization remains valid for [one] year, starting from September 28th.2023 and expiring on September 27th.2024.

Name: Yifan Wang

Title: Regional Sales Manager

Signature: