

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2181711DE02

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

Manufacturer:

Bioptimal International PTE. LTD.

**36 Jalan Tukang
619266 Singapore
Singapore**

For the product

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

Documents, that form the basis of this certificate:

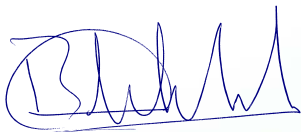
Certification Notice 2181711CN, initially dated 15 July 2015
Addendum, initially dated 15 July 2015

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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: 1 April 2020

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2181711DE02

1/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

Issued to:

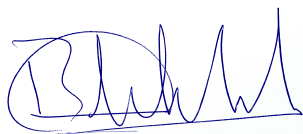
Bioptimal International PTE. LTD.
36 Jalan Tukang
619266 Singapore
Singapore

This certificate covers the following product(s):

THERMODILUTION CATHETER – MODEL REFERENCES

<i>Thermodilution Catheter Generic Model reference</i>	
TD1504 TD 1504-110 TD1604 TD1704 TD1755	Polyvinylchloride tubing
TD2504 TD 2504-110 TD2604 TD2704 TD2755	Polyurethane tubing

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2181711DE02

2/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

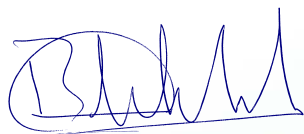
Issued to:

Bioptimal International PTE. LTD.

36 Jalan Tukang
619266 Singapore
Singapore

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

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2181711DE02

3/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

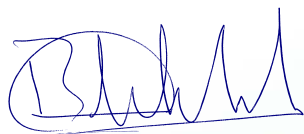
Issued to:

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

PULMONARY ARTERY MONITORING CATHETER – MODEL REFERENCES

<i>Pulmonary Artery Monitoring Catheter Generic Model reference</i>	
TD1502	Polyvinylchloride tubing
TD 1502-110	
TD1602	
TD1702	
TD1603	
TD1703	Polyurethane tubing
TD2502	
TD 2502-110	
TD2602	
TD2702	
TD2603	
TD2703	

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2181711DE02

4/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

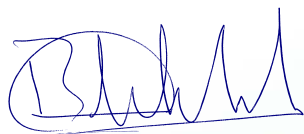
Issued to:

Bioptimal International PTE. LTD.

36 Jalan Tukang
619266 Singapore
Singapore

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

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2181711DE02

5/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

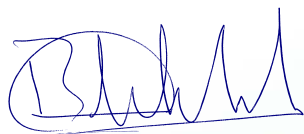
Issued to:

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

BIOTRAY – MODEL REFERENCES

<i>Biotray</i> <i>Generic Model reference</i>	
BIOTRAY TD1504	Biotray with Thermodilution Catheter
BIOTRAY TD1504-110	
BIOTRAY TD1604	
BIOTRAY TD1704	
BIOTRAY TD1755	
BIOTRAY TD2504	
BIOTRAY TD2504-110	
BIOTRAY TD2604	
BIOTRAY TD2704	
BIOTRAY TD2755	
BIOTRAY TD1502	Biotray with Pulmonary Artery Monitoring Catheter
BIOTRAY TD1502-110	
BIOTRAY TD1602	
BIOTRAY TD1702	
BIOTRAY TD1603	
BIOTRAY TD1703	

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2181711DE02

6/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

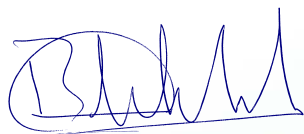
Issued to:

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

BIOTRAY TD2502
BIOTRAY TD2502-110
BIOTRAY TD2602
BIOTRAY TD2702
BIOTRAY TD2603
BIOTRAY TD2703

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

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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: 2181711DE02

7/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

Issued to:

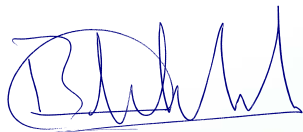
Bioptimal International PTE. LTD.
36 Jalan Tukang
619266 Singapore
Singapore

Rubber boot	B
-------------	---

Initial date: 15 July 2015

Revision date: 6 May 2020

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

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