

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:

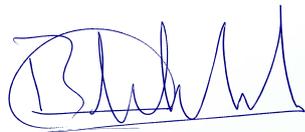
Certification Notice 2181711CN, initially dated 15 July 2015
Addendum, initially dated 15 July 2015

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

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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: 2181711DE02

1/7

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

Issued to:

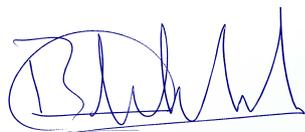
Bioptimal International PTE. LTD.
36 Jalan Tukang
619266 Singapore
Singapore

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

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

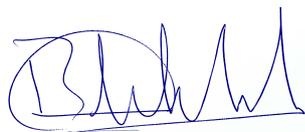
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Optional Features	Suffix
Safetywedge™	D
Contamination Sleeve	X
Non-coated tubing	N
Soft Body Tubing	S
Stiff Body Tubing	F
Zebra Numerical Print	Z
S-Tip Guide	C
Medication port	AV
Proximal port	M
Proximal port	G
Pacing extension	P
Longer thermistor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

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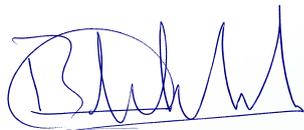
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PULMONARY ARTERY MONITORING CATHETER – MODEL REFERENCES

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

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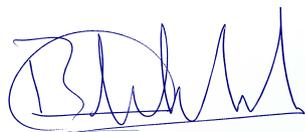
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Optional Features	Suffix
Safetywedge™	D
Contamination Sleeve	X
Non-coated tubing	N
Soft Body Tubing	S
Stiff Body Tubing	F
Zebra Numerical Print	Z
S-Tip Guide	C
Medication port	AV
Proximal port	M
Proximal port	G
Pacing extension	P
Longer thermistor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

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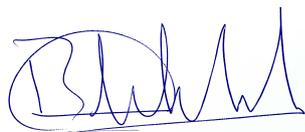
Bioptimal International PTE. LTD.

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BIOTRAY – MODEL REFERENCES

<i>Biotray</i> <i>Generic Model reference</i>	
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
BIOTRAY TD1502 BIOTRAY TD1502-110 BIOTRAY TD1602 BIOTRAY TD1702 BIOTRAY TD1603 BIOTRAY TD1703	Biotray with Pulmonary Artery Monitoring Catheter

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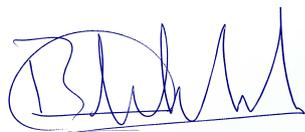
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BIOTRAY TD2502
 BIOTRAY TD2502-110
 BIOTRAY TD2602
 BIOTRAY TD2702
 BIOTRAY TD2603
 BIOTRAY TD2703

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

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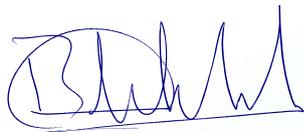
Bioptimal International PTE. LTD.
36 Jalan Tukang
619266 Singapore
Singapore

Rubber boot B

Initial date: 15 July 2015

Revision date: 6 May 2020

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A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' followed by 'A. van Vugt' in a cursive style.

J.A. van Vugt
Certification Manager

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