

TÜV SÜD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT ◆ CERTIFICAT



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-200.14.03



Product Service

## EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
(Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0194 Rev. 01**

**Manufacturer:** **St. Jude Medical**  
**Cardiac Rhythm Management**  
**Division**  
15900 Valley View Court  
Sylmar CA 91342  
USA

**Product:** **Leads for Tachy IPGs and their auxiliary components**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

**Report no.:** 713168380

**Valid from:** 2020-03-04

**Valid until:** 2024-05-26

**Date,** 2020-03-04

Christoph Dicks  
Head of Certification/Notified Body

Page 1 of 4

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0194 Rev. 01**

**Model(s):** see below

**Product:** Leads for Tachy IPGs and their auxiliary components

**Test Report No.:** 713050175, 71326511

Model:	Model no.:	Length [cm]:	Variant:
Durata™	7120	60	
		65	
		75	
	7121	60	
		65	
		75	
	7122	60	
		65	
		75	
7170	60		
	65		
	75		
7171	60		
	65		
	75		

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0194 Rev. 01**

Test Report No.: 713050175, 71327993, 713057341

Model:	Model no.:	Length [cm]:	Variant:	
Durata™	7120Q	52	MR Conditional MR Conditional	
		58		
		65		
	7121Q	52		
		58		
		65		
	7122Q	52	MR Conditional MR Conditional	
		58		
		65		
	7170Q	52		
		58		
		65		
	7171Q	52		
		58		
		65		
	7172Q	52		
		58		
		65		

Test Report No.: 713050175, 713015987\_2

Model:	Model no.:	Length [cm]:	Variant:
Optisure™	LDA220	60	
		65	
		75	
	LDA230	60	
		65	
		75	

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EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0194 Rev. 01**

LDA210	60
	65
	75
LDP220	60
	65
	75
LDP230	60
	65
	75

Test Report No.: 713050175, 713015987\_2, 713057341

Model:	Model no.:	Length [cm]:	Variant:
Optisure™	LDA220Q	52	
		58	MR Conditional
		65	MR Conditional
	LDA230Q	52	
		58	
		65	
	LDA210Q	52	
		58	MR Conditional
		65	MR Conditional
	LDP220Q	52	
		58	
		65	
	LDP230Q	52	
		58	
		65	
	LDP210Q	52	
		58	
		65	



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Product Service

# EC Certificate

EC Design-Examination Certificate  
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
(Other devices than custom made or intended for clinical investigation)  
**No. I7 014607 0200 Rev. 01**

**Model(s):** see next page

**Facility(ies):**  
St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court, Sylmar CA 91342, USA  
  
St. Jude Medical Puerto Rico LLC  
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo  
PR 00612, USA  
  
St. Jude Medical Operations (M) Sdn.Bhd.  
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial  
Zone, 11900 Penang, MALAYSIA

**Design Facility(ies)** St. Jude Medical Cardiac Rhythm Management Division,  
15900 Valley View Court, Sylmar, CA 91342, USA

**Parameters:** ./.





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Product Service

## EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0200 Rev. 01**

### Product: Leads for Brady IPGs and their auxiliary components

Test Report No.: 71346063

Model:	Model No:	Length: [cm]	Variant:
AV Plus® DX	1368	52 58 65	

Test Report No.: 71333914

Model:	Model No:	Length: [cm]	Variant:
OptiSense™	1999	46 52	

Test Report No.: 71336638

Model:	Model No:	Length: [cm]	Variant:
QuickFlex™µ	1258T	75 86 92	

Test Report No.: 71355744

Model:	Model No:	Length: [cm]	Variant:
Quartet	1458Q	75 92	



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## EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0200 Rev. 01**

Test Report No.: 71351838

Model:	Model No:	Length: [cm]	Variant:
Tendril™ STS	2088TC	65 100	

Test Report No.: 713035264

Model:	Model No:	Length: [cm]	Variant:
Tendril™ STS	2088TC	46 52 58	MR Conditional MR Conditional MR Conditional
IsoFlex™	1944	46 52	MR Conditional MR Conditional
	1948	52 58	MR Conditional MR Conditional

Test Report No.: 71355744/ 713068024

Model:	Model No:	Length: [cm]	Variant:
Quartet	1458Q	86	MR Conditional

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# EC Certificate

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 Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0200 Rev. 01**

Test Report No.: 713068167

Model:	Model No:	Length: [cm]	Variant:
Quartet	1456Q	75	MR Conditional
	1457Q	75	
	1458QL	86	MR Conditional
		75	MR Conditional
	86	MR Conditional	

Test Report No.: 713097198

Model:	Model No:	Length: [cm]	Variant:
Tendril MRI	LPA1200M	46	MR Conditional
		52	MR Conditional
		58	MR Conditional





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# EC Certificate

EC Design-Examination Certificate  
 Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)  
**No. I7 014607 0238 Rev. 00**

**Model(s):** see below

**Facility(ies):**

- St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court, Sylmar CA 91342, USA
- St. Jude Medical Puerto Rico LLC  
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo PR 00612, USA
- St. Jude Medical Operations (M) Sdn.Bhd.  
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA

**Design Facility(ies):** St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court, Sylmar, CA 91342, USA

**Product:** Implantable Cardioverter / Defibrillators

**Test Report No.:** 713171090\_1

Model:	Model no.:	Variant:
Avant™ VR	CDVRA700Q	MR Conditional
Gallant™ VR	CDVRA500Q	MR Conditional
Entrant™ VR	CDVRA300Q	MR Conditional
Neutrino™ NxT VR	CDVRA800Q	MR Conditional
Neutrino™ NxT VR	CDVRA600Q	MR Conditional
Avant™ DR	CDDRA700Q	MR Conditional
Gallant™ DR	CDDRA500Q	MR Conditional
Entrant™ DR	CDDRA300Q	MR Conditional

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EC Design-Examination Certificate  
 Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0238 Rev. 00**

Neutrino™ NxT DR	CDDRA800Q	MR Conditional
Neutrino™ NxT DR	CDDRA600Q	MR Conditional
Avant™ HF	CDHFA700Q	MR Conditional
Gallant™ HF	CDHFA500Q	MR Conditional
Entrant™ HF	CDHFA300Q	MR Conditional
Neutrino™ NxT HF	CDHFA800Q	MR Conditional
Neutrino™ NxT HF	CDHFA600Q	MR Conditional

**Product: Patient Mobile Application**

**Test Report No.:** 713171090\_2

<b>Model:</b>	<b>Model no.:</b>	<b>Variant:</b>
myMerlinPulse™	APP1004	Android
myMerlinPulse™	APP1005	iOS



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BS-MDR-099



Product Service

## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
(Implantable Class IIb Devices and Class III Devices)

**No. G70 014607 0259 Rev. 00**

**Manufacturer:**

**Abbott Medical**

15900 Valley View Court  
Sylmar CA 91342  
USA

**SRN Manufacturer:**

US-MF-000010383

**Authorized  
Representative:**

Abbott Medical  
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,  
BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G70\\_014607\\_0259\\_Rev\\_00](http://www.tuvsud.com/ps-cert?q=cert:G70_014607_0259_Rev_00)

**Report No.:** 713224043

**Valid from:** 2022-11-15

**Valid until:** 2027-11-14

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-11-15



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BS-MDR-099



Product Service

## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
(Implantable Class IIb Devices and Class III Devices)

**No. G70 014607 0259 Rev. 00**

**Classification:** III  
**Device Group:** J010201 - IMPLANTABLE DIAGNOSTIC ARRHYTHMIAS  
RECORDING CARDIAC DEVICES  
**Basic UDI-DI:** 5415067CMD0002AK  
**Intended Purpose:** The Jot Dx™ ICM is intended to help physicians and clinicians  
monitor, diagnose and document the heart rhythm in patients who  
are susceptible to cardiac arrhythmias and unexplained symptoms  
by detecting arrhythmias and transmitting data for review.

**Device(s):** Jot Dx™ - DM4500

**Classification:** III  
**Device Group:** J01900282 - IMPLANTABLE CARDIAC DEVICES  
PROGRAMMERS - SOFTWARE ACCESSORY  
**Basic UDI-DI:** 5415067CMD0002AK  
**Intended Purpose:** The myMerlin™ mobile application is intended for people who  
have a Jot Dx™ ICM or Confirm Rx™ ICM and access to a mobile  
device. The app allows the patient to activate recordings in the  
implanted device and wirelessly transmit data for physician and  
clinician review.

**Device(s):** myMerlin™ mobile app - APP1001 (iOS),  
myMerlin™ mobile app - APP1000 (Android)

**The validity of this certificate depends on conditions and/or is limited to the following:** ./.



## MDR Declaration of Conformity

<b>Manufacturer:</b>	St. Jude Medical Cardiac Rhythm Management Division
<b>Manufacturer SRN:</b>	US-MF-000010382
<b>Address:</b>	15900 Valley View Court Sylmar, CA 91342 USA
<b>Manufacturing Site(s):</b>	15900 Valley View Court Sylmar, CA 91342 USA  St. Jude Medical Operations (M) Sdn.Bhd. Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, Malaysia
<b>European Authorized Representative:</b>	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
<b>European Authorized Representative SRN:</b>	BE-AR-000008417

This declaration of conformity is issued under the sole responsibility of the manufacturer.

<b>Product Type:</b>	Implantable Monitoring and Recording Systems
<b>Product Trade Name(s):</b>	Confirm Rx™ myMerlin™
<b>Model Number(s):</b>	DM3500, APP1000, APP1001
<b>Intended Purpose:</b>	The Confirm Rx™ ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.

<b>Signature:</b>  Colleen Canan Divisional Vice President Regulatory Affairs	Digitally signed by CANANCX Date: 2022.04.18 16:25:07 -07'00'  <b>April 18, 2022</b> Issue Date  On behalf of St. Jude Medical Cardiac Rhythm Management Division, signed at Sylmar, CA
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## MDR Declaration of Conformity

	The myMerlin™ mobile application is intended for people who have a Confirm Rx ICM and access to a mobile device. The app allows the patient to activate recordings in the implanted device and wirelessly transmit data for physician and clinician review.
<b>Risk Classification:</b>	<ul style="list-style-type: none"> <li>Confirm Rx™ ICM DM3500: Class III per EU MDR 2017/745 Annex VIII</li> <li>myMerlin™ APP1000, APP1001: Class III per EU MDR 2017/745 Annex VIII</li> </ul>
<b>Classification Rationale:</b>	<ul style="list-style-type: none"> <li>Confirm Rx™ ICM DM3500: Rule 8, as a long term, surgically invasive, active implantable medical device.</li> <li>myMerlin™ APP1000, APP1001: Rule 11, Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause death or an irreversible deterioration of a person's state of health, in which case it is in Class III.</li> </ul>
<b>EMDN Code(s):</b>	DM3500: J010201 APP1000, APP1001: J01900282
<b>Basic UDI-DI:</b>	5415067CMD0001AH

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

<b>Common Specifications Applied:</b>	N/A
<b>STED #</b>	90626180
<b>Notified Body:</b>	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany NB #: 0123
<b>Supporting Certificate(s):</b>	TDAC Certificate No: G70 014607 0249 Rev. 00 Expiration Date: 2026-12-12  QMS Certificate No: G12 014607 0244 Rev. 02 Expiration Date: 2026-04-06



## MDR Declaration of Conformity

<b>Original CE Mark Date:</b>	<b>Device Name</b>	<b>Original CE Mark Date (AIMDD)</b>
	Confirm Rx™ - Insertable Cardiac Monitor DM3500	December 16, 2016
	myMerlin™ mobile application APP1000 (Android)	December 16, 2016
	myMerlin™ mobile application APP1001 (iOS)	April 06, 2017
<b>Conformity Assessment:</b>	Annex IX	
<b>Device Photograph:</b>	Figure 1: Confirm Rx™ ICM DM3500 Picture, Figure 2: Confirm Rx™ ICM DM3500 Packaging Configuration, Picture	

## MDR Declaration of Conformity



Figure 1: Confirm Rx™ ICM DM3500, Picture

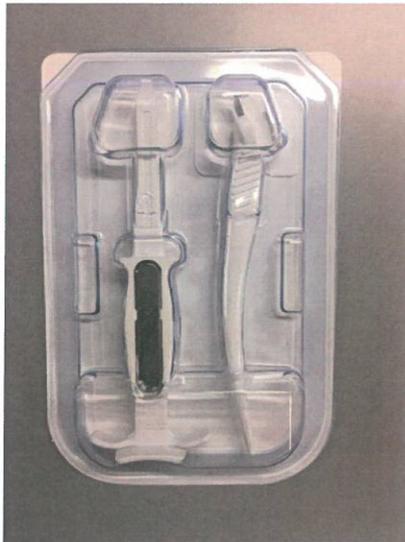


Figure 2: Confirm Rx™ ICM DM3500, Packaging Configuration with IC preloaded in Insertion Tool



St. Jude Medical  
Cardiac Rhythm Management Division 15900 Valley View Ct.  
Sylmar, CA 91342  
Tel: +1 408 522 6464  
Fax: 1-818-364-5814

16741 Rev. C

## MDR Declaration of Conformity

The products in the attached Declaration of Conformity Product List are approved under EC Certificate No. G70 014607 0249 Rev. 00.

### Declaration of Conformity Product List

Model No.	Description	UDI-DI
DM3500	Confirm Rx™ Insertable Cardiac Monitor	05415067027320
APP1000 (Android)	myMerlin™ mobile application	05415067027399
APP1001 (iOS)	myMerlin™ mobile application	05415067027405

The signature is applied on page 1  
88136 MDR Declaration of Conformity Template Rev F

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## SJM Declaration of Conformity Pacing System Analyzer and their Auxiliary Components

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

**Manufacturer Address:** *St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court  
Sylmar, CA 91342, USA*

**European Representative:** *St. Jude Medical Coordination Center BVBA  
The Corporate Village  
Da Vincilaan 11 Box F1  
1935 Zaventem, Belgium*

**Product Type:** *Pacing System Analyzer and their Auxiliary Components*

**Product Name(s):** *See Attachment*

**Model Number(s):** *See Attachment*

**Classification:** *AIMD*

**GMDN Code(s):** *See Attachment*

**Original CE Mark Date:** *See Attachment*

**Certificate No. and expiration date:** *EC Certification No: I7 014607 0235 Rev. 01  
Expiration Date: 2024-05-26*

*FQA  
Certificate No: I1 014607 0211 Rev. 01  
Expiration Date: 2024-05-26*

*EN ISO 13485:2016  
Certificate No: Q5 014607 0231 Rev. 00  
Expiration Date: 2022-03-31*

**Signature:**

  
Kathy Berg  
Sr. Manager Regulatory Affairs

  
Issue Date

**SJM Declaration of Conformity  
Pacing System Analyzer and their Auxiliary Components**

**Applicable Quality System Standards:** Fulfills the requirements of Annex 2 of the European Union's Active Medical Devices Directive, AIMDD, 90/385/EEC/corresponding national legislation

Fulfills applicable requirements including CE marking and the Essential Requirements of AIMDD, 90/385/EEC/corresponding national legislation

**Notified Body:** TÜV SÜD Product Service GmbH Zertifizierstelle  
Ridlerstraße 65, 80339, München, Germany

**Notified Body Number:** 0123

**Manufacturing Facilities:** *St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court Sylmar, CA 91342, USA*

**Signature:**

  
Kathy Berg  
Sr. Manager Regulatory Affairs

  
Issue Date

**SJM Declaration of Conformity**  
**Pacing System Analyzer and their Auxiliary Components**  
**ATTACHMENT TO DECLARATION OF CONFORMITY**

The following product(s) is/are approved under EC Certificate Number I7 014607 0235 Rev. 01.

Product Name	Model Number	GMDN Code	First Date of CE Marking
Disposable surgical cable	4161	47143	2009-9-1
Merlin PSA	EX3100	31700	2010-3-4
Merlin PSA Cable Adapter	EX3170	31700	2010-3-4
Merlin PSA "M" Adapter	EX3180	31700	2010-3-4
Merlin Antenna Adapter	EX3190	31700	2010-3-4
Disposable surgical cable	4051L	47143	2012-2-24
Merlin PSA Patient Cable	EX3150	47143	2010-12-09

Signature:

  
 \_\_\_\_\_  
 Kathy Berg  
 Sr. Manager Regulatory Affairs

  
 \_\_\_\_\_  
 Issue Date

## SJM Declaration of Conformity Leads for Tachy IPGs and their Auxiliary Components

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

<b>Manufacturer Address:</b>	<i>St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, CA 91342, USA</i>
<b>European Representative:</b>	<i>St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium</i>
<b>Product Type:</b>	<i>Leads for Tachy IPGs and their Auxiliary Components</i>
<b>Product Name(s):</b>	<i>See Attachment</i>
<b>Model Number(s):</b>	<i>See Attachment</i>
<b>Classification:</b>	<i>AIMD</i>
<b>GMDN Code(s):</b>	<i>See Attachment</i>
<b>Original CE Mark Date:</b>	<i>See Attachment</i>
<b>Certificate No. and expiration date:</b>	<i>EC Certification No: I7 014607 0194 Rev. 01 Expiration Date: 2024-05-26</i>  <i>FQA Certificate No: I1 014607 0211 Rev. 01 Expiration Date: 2024-05-26</i>  <i>EN ISO 13485:2016 Certificate No: Q5 014607 0231 Rev. 00 Expiration Date: 2022-03-31</i>

**Signature:**

  
Kathy Berg  
Sr. Manager Regulatory Affairs

  
Issue Date

## SJM Declaration of Conformity Leads for Tachy IPGs and their Auxiliary Components

<b>Applicable Quality System Standards:</b>	Fulfills the requirements of Annex 2 of the European Union's Active Medical Devices Directive, AIMDD, 90/385/EEC/corresponding national legislation
	Fulfills applicable requirements including CE marking and the Essential Requirements of AIMDD, 90/385/EEC/corresponding national legislation
<b>Notified Body:</b>	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65, 80339, München, Germany
<b>Notified Body Number:</b>	0123
<b>Manufacturing Facilities:</b>	<i>St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, CA 91342, USA</i> <i>St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo PR 00162, US</i> <i>St. Jude Medical Operations (M) Sdn.Bhd Plot 102, Ledbuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA</i>

**Signature:**  
Kathy Berg  
Sr. Manager Regulatory Affairs  
Issue Date

**SJM Declaration of Conformity**  
**Leads for Tachy IPGs and their Auxiliary Components**  
**ATTACHMENT TO DECLARATION OF CONFORMITY**

The following product(s) is/are approved under EC Certificate Number I7 014607 0194 Rev. 01.

Product Name	Lead Model	Length (cm)	GMDN Code	First Date of CE Marking
Durata	7120, 7121, 7122	60, 65, 75	35853	2007-11-23
	7170, 7171	60, 65, 75		
	7120Q	52		2009-09-01
	7120Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	7121Q	52, 58, 65		2009-09-01
	7122Q	52		2009-09-01
	7122Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	7170Q, 7171Q, 7172Q	52, 58, 65		2009-09-01
Optisure	LDA210, LDA220, LDA230	60, 65, 75		2012-12-19
	LDP220 LDP230	60, 65, 75		2012-12-19

Signature:



Kathy Berg  
Sr. Manager Regulatory Affairs

22 Apr 2020  
Issue Date

### SJM Declaration of Conformity Leads for Tachy IPGs and their Auxiliary Components

Product Name	Lead Model	Length (cm)	GMDN Code	First Date of CE Marking
Optisure	LDA220Q	52	35853	2012-12-19
	LDA220Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	LDA230Q	52, 58, 65		2012-12-19
	LDA210Q	52		2012-12-19
	LDA210Q	58 (MR Conditional) 65 (MR Conditional)		2015-05-11
	LDP210Q, LDP220Q, LDP230Q	52, 58, 65		2012-12-19

**Signature:**

  
 Kathy Berg  
 Sr. Manager Regulatory Affairs

  
 Issue Date

## SJM Declaration of Conformity Implantable Cardioverter / Defibrillator Systems

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

**Manufacturer Address:** *St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court  
Sylmar, CA 91342, USA*

**European Representative:** *St. Jude Medical Coordination Center BVBA  
The Corporate Village  
Da Vincilaan 11 Box F1  
1935 Zaventem, Belgium*

**Product Type:** *Implantable Cardioverter / Defibrillator Systems*

**Product Name(s):** *See Attachment*

**Model Number(s):** *See Attachment*

**Classification:** *AIMD*

**GMDN Code(s):** *See Attachment*

**Original CE Mark Date:** *See Attachment*

**Certificate No. and expiration date:** *EC Certification No: I7 014607 0238 Rev. 00  
Expiration Date: 2024-05-26*

*FQA  
Certificate No: I1 014607 0211 Rev. 01  
Expiration Date: 2024-05-26*

*EN ISO 13485:2016  
Certificate No: Q5 014607 0231 Rev. 00  
Expiration Date: 2022-03-31*

**Signature:**

  
Kathy Berg  
Sr. Manager Regulatory Affairs

  
Issue Date

**SJM Declaration of Conformity  
Implantable Cardioverter / Defibrillator Systems****Applicable Quality System Standards:**

Fulfills the requirements of Annex 2 of the European Union's Active Medical Devices Directive, AIMDD, 90/385/EEC/corresponding national legislation

Fulfills applicable requirements including CE marking and the Essential Requirements of AIMDD, 90/385/EEC/corresponding national legislation

**Notified Body:**

*TÜV SÜD Product Service GmbH Zertifizierstelle  
Ridlerstraße 65, 80339, München, Germany*

**Notified Body Number:**

0123

**Manufacturing Facilities:**

*St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court Sylmar, CA 91342, USA*

*St. Jude Medical Puerto Rico LLC  
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park,  
Arecibo PR 00162, USA*

*St. Jude Medical Operations (M) Sdn.Bhd  
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas  
Industrial Zone, 11900 Penang, MALAYSIA*

**Signature:**

  
Kathy Berg  
Sr. Manager Regulatory Affairs

  
Issue Date

**SJM Declaration of Conformity**  
**Implantable Cardioverter / Defibrillator Systems**  
**ATTACHMENT TO DECLARATION OF CONFORMITY**

The following product(s) is/are approved under EC-Certificate number I7 014607 0238 Rev. 00.

Product Name	Model No.	Variant	GMDN Code	First Date of CE Marking
<b>Implantable Cardioverter / Defibrillators</b>				
Avant™ VR	CDVRA700Q	MR Conditional	35852	2019-12-11
Gallant™ VR	CDVRA500Q	MR Conditional	35852	2019-12-11
Entrant™ VR	CDVRA300Q	MR Conditional	35852	2019-12-11
Neutrino™ NxT VR	CDVRA800Q	MR Conditional	35852	2019-12-11
Neutrino™ NxT VR	CDVRA600Q	MR Conditional	35852	2019-12-11
Avant™ DR	CDDRA700Q	MR Conditional	37265	2019-12-11
Gallant™ DR	CDDRA500Q	MR Conditional	37265	2019-12-11
Entrant™ DR	CDDRA300Q	MR Conditional	37265	2019-12-11
Neutrino™ NxT DR	CDDRA800Q	MR Conditional	37265	2019-12-11
Neutrino™ NxT DR	CDDRA600Q	MR Conditional	37265	2019-12-11
Avant™ HF	CDHFA700Q	MR Conditional	47270	2019-12-11
Gallant™ HF	CDHFA500Q	MR Conditional	47270	2019-12-11
Entrant™ HF	CDHFA300Q	MR Conditional	47270	2019-12-11
Neutrino™ NxT HF	CDHFA800Q	MR Conditional	47270	2019-12-11
Neutrino™ NxT HF	CDHFA600Q	MR Conditional	47270	2019-12-11
<b>Patient Application</b>				
myMerlinPulse™	APP1004	Android	61680	2019-12-11
myMerlinPulse™	APP1005	iOS	61680	2019-12-11

Signature:



Kathy Berg  
 Sr. Manager Regulatory Affairs

22 Apr 2020  
 Issue Date

## SJM Declaration of Conformity Leads for Brady IPGs and Their Auxiliary Components

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

<b>Manufacturer Address:</b>	<i>St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, CA 91342, USA</i>
<b>European Representative:</b>	<i>St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium</i>
<b>Product Type:</b>	<i>Leads for Brady IPGs and Their Auxiliary Components</i>
<b>Product Name(s):</b>	<i>See Attachment</i>
<b>Model Number(s):</b>	<i>See Attachment</i>
<b>Classification:</b>	<i>AIMD</i>
<b>GMDN Code(s):</b>	<i>See Attachment</i>
<b>Original CE Mark Date:</b>	<i>See Attachment</i>
<b>Certificate Nos. and expiration dates:</b>	<i>EC Certification No: I7 014607 0200 Rev. 01 Expiration Date: 2024-01-20  FQA Certificate No: I1 014607 0211 Rev. 01 Expiration Date: 2024-05-26  EN ISO 13485:2016 Certificate No: Q5 014607 0231 Rev. 00 Expiration Date: 2022-03-31</i>

**Signature:**  
Kathy Berg  
Sr. Manager Regulatory Affairs  
Issue Date



## SJM Declaration of Conformity Leads for Brady IPGs and Their Auxiliary Components

**Applicable Quality System Standards:**

Fulfills the requirements of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC and corresponding national legislation

Fulfills applicable requirements including CE marking and the Essential Requirements of the AIMDD, 90/385/EEC and corresponding national legislation

**Notified Body:**

TÜV SÜD Product Service GmbH Zertifizierstelle  
Ridlerstraße 65, 80339, München, Germany

**Notified Body Number:**

0123

**Manufacturing Facilities:**

*St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court Sylmar, CA 91342 USA*

*St. Jude Medical Puerto Rico LLC  
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park,  
Arecibo PR 00612, USA*

*St. Jude Medical Operations (M) Sdn. Bhd  
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas  
Industrial Zone, 11900 Penang, MALAYSIA*

**Signature:**

Kathy Berg  
Sr. Manager Regulatory Affairs

Issue Date

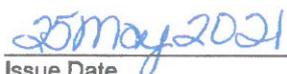
**SJM Declaration of Conformity**  
**Leads for Brady IPGs and Their Auxiliary Components**  
**ATTACHMENT TO DECLARATION OF CONFORMITY**

The following product(s) is/are approved under EC-certificate number I7 014607 0200 Rev. 01:

Product Name	Model No.	Length	GMDN Codes	First Date of CE Marking
AV Plus® DX	1368	52, 58, 65	35223	20-Jan-1999
IsoFlex™	1944 (MR Conditional)	46, 52	35223	2-Feb-2015
IsoFlex™	1948 (MR Conditional)	52, 58	35223	2-Feb-2015
OptiSense™	1999	46, 52	35223	29-Apr-2008
Quartet	1456Q	75	35223	18-Dec-2015
Quartet	1456Q (MR Conditional)	86	35223	18-Dec-2015
Quartet	1457Q	75	35223	18-Dec-2015
Quartet	1457Q (MR Conditional)	86	35223	18-Dec-2015
Quartet	1458Q	75	35223	30-Sep-2009
Quartet	1458Q (MR Conditional)	86	35223	13-Oct-2015
Quartet	1458Q	92	35223	30-Sep-2009
Quartet	1458QL	75	35223	18-Dec-2015
Quartet	1458QL (MR Conditional)	86	35223	18-Dec-2015
QuickFlex™ μ	1258T	75, 86, 92	35223	29-Sep-2008
Tendril™ MRI	LPA1200M (MR Conditional)	46, 52, 58	35223	23-Feb-2011
Tendril™ STS	2088TC	65, 100	35223	06-Oct-2011
Tendril™ STS	2088TC (MR Conditional)	46, 52, 58	35223	2-Feb-2015

Signature:

  
 Kathy Berg  
 Sr. Manager Regulatory Affairs

  
 Issue Date



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BS-MDR-099



Product Service

## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
(Implantable Class IIb Devices and Class III Devices)

**No. G70 014607 0249 Rev. 00**

**Manufacturer:** **St. Jude Medical**  
**Cardiac Rhythm Management**  
**Division**  
15900 Valley View Court  
Sylmar CA 91342  
USA

**SRN Manufacturer:** US-MF-000010382

**Authorized Representative:** St. Jude Medical Coordination Center BVBA  
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,  
BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G70\\_014607\\_0249\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G70_014607_0249_Rev.00)

**Report No.:** 713194597, 713199649

**Valid from:** 2021-12-13

**Valid until:** 2026-12-12

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2021-12-13





TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



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Product Service

# EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0234 Rev. 01**

**Model(s):** see below

**Facility(ies):** St. Jude Medical Cardiac Rhythm Management Division  
 15900 Valley View Court, Sylmar CA 91342, USA

St. Jude Medical Puerto Rico LLC  
 Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo  
 PR 00612, USA

St. Jude Medical Operations (M) Sdn.Bhd.  
 Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone,  
 11900 Penang, MALAYSIA

**Parameters** ./.

**Design Facility(ies):** St. Jude Medical Cardiac Rhythm Management Division  
 15900 Valley View Court, Sylmar, CA 91342, USA

**Product:** Implantable Pacemakers

Test Report No.: 70069297

Model:	Model No.:	Variant:
Microny™ II SR+	2525T	

Test Report No.: 70110810

Model:	Model No.:	Variant:
Zephyr™ SR	5620	
Zephyr™ DR	5820	
Zephyr™ XL DR	5826	

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



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Product Service

# EC Certificate

EC Design-Examination Certificate  
 Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0234 Rev. 01**

Test Report No.: 71321436

Model:	Model No.:	Variant:
Zephyr™ XL SR	5626	

Test Report No.: 713017309\_1

Model:	Model No.:	Variant:
Assurity™	PM1240	
Assurity™	PM2240	
Endurity™	PM1160	
Endurity™	PM2160	
Allure™	PM3120	
Allure™ RF	PM3222	
Allure Quadra™ RF	PM3242	

Test Report No.: 713028360

Model:	Model No.:	Variant
Quadra Allure MP™RF	PM3262	

Test Report No.: 713043621

Model:	Model No.:	Variant:
Assurity MRI™	PM1272	MR Conditional
Assurity MRI™	PM2272	MR Conditional
Endurity MRI™	PM1172	MR Conditional
Endurity MRI™	PM2172	MR Conditional
Endurity™	PM1162	MR Conditional
Endurity™	PM2162	MR Conditional





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Product Service

# EC Certificate

EC Design-Examination Certificate  
 Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)  
**No. I7 014607 0234 Rev. 01**

Test Report No.: 713057320

Model:	Model No.:	Variant:
Endurity™ Core	PM1140	MR Conditional
Endurity™ Core	PM2140	MR Conditional
Endurity™ Core	PM1152	MR Conditional
Endurity™ Core	PM2152	MR Conditional

Test Report No.: 713084189

Model:	Model No.:	Variant:
Quadra Allure™	PM3542	MR Conditional
Quadra Allure MP™	PM3562	MR Conditional

Test Report No.: 713130819

Model:	Model No.:	Variant:
Zenex™	PM1250	
Zenex™	PM2250	
Zenus™	PM1170	
Zenus™	PM2170	
Zenex MRI™	PM1282	MR Conditional
Zenex MRI™	PM2282	MR Conditional
Zenus MRI™	PM1182	MR Conditional
Zenus MRI™	PM2182	MR Conditional

Test Report No.: 713167182

Model:	Model No.:	Variant:
Verity™ ADx XL VDR	5456	





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Product Service

## EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)  
 (Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0235 Rev. 01**

<b>Model(s):</b>	<b>see below</b>
<b>Product:</b>	<b>Pacing System Analyzer and their auxiliary components</b>
<b>Test Report No.:</b>	71327994
<b>Model:</b> Disposable surgical cable	<b>Model no.:</b> 4161
<b>Test Report No.:</b>	71364725
<b>Model:</b> Merlin PSA Merlin PSA Cable Adapter Merlin PSA "M" Adapter Merlin Antenna Adapter	<b>Model no.:</b> EX3100 EX3170 EX3180 EX3190
<b>Test Report No.:</b>	71394312
<b>Model:</b> Disposable surgical cable	<b>Model no.:</b> 4051L
<b>Test Report No.:</b>	71372746, 713156176, 713174689
<b>Model:</b> Merlin PSA Patient Cable	<b>Model no.:</b> EX3150



## MDR Declaration of Conformity

<b>Manufacturer:</b>	Abbott Medical
<b>Manufacturer SRN:</b>	US-MF-000010383
<b>Address:</b>	15900 Valley View Court Sylmar, CA 91342 USA
<b>Manufacturing Site(s):</b>	Abbott Medical 15900 Valley View Court Sylmar, CA 91342 USA  Abbott Medical Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo, PR 00612 USA  Abbott Medical Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang Malaysia
<b>European Authorized Representative:</b>	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium
<b>European Authorized Representative SRN:</b>	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

<b>Product Type:</b>	Implantable Cardioverter Defibrillator
<b>Product Trade Name(s):</b>	See attached Product List
<b>Model Number(s):</b>	See attached Product List

<b>Signature:</b>  Colleen Canan Divisional Vice President, Global Regulatory Affairs, Cardiac Rhythm Management	Digitally signed by CANANCX Date: 2022.08.17 12:24:03 -07'00'  August 17, 2022 Issue Date On behalf of Abbott Medical, signed at Sylmar, California, USA
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## MDR Declaration of Conformity

<b>Intended Purpose:</b>	<p><b>IMPLANTABLE SINGLE CHAMBER AND DUAL CHAMBER DEFIBRILLATORS</b>          The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, ICD devices can detect and treat</p> <ul style="list-style-type: none"> <li>• <b>chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle</b></li> <li>• <b>various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium</b></li> </ul> <p><b>IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS</b>          The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, these devices can detect and treat chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.          CRT-D devices sense cardiac activity and provide pacing to resynchronize the right and left ventricles.</p>
<b>Risk Classification:</b>	<b>Class III</b> as per EU MDR 2017/745 per Annex VIII
<b>Classification Rationale:</b>	Annex VIII, Rule 8_6, as a long term, surgically invasive, active implantable medical device
<b>EMDN Code(s):</b>	See attached Product List
<b>Basic UDI-DI:</b>	See attached Product List

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

<b>Common Specifications Applied:</b>	Not Applicable. No common specifications are available for this type of device
<b>STED #</b>	TD 01-21, Windchill ID: 43801



## MDR Declaration of Conformity

<b>Notified Body:</b>	TÜV SÜD Product Services GmbH Ridlerstraße 65 80339 Munich Germany ID Number: 0123
<b>Supporting Certificate(s):</b>	Quality Management System Certificate: G12 014607 0255 Rev. 00 Expiration Date: 2027-08-14  Technical Documentation Assessment Certificate: G70 014607 0257 Rev. 00 Expiration Date: 2027-08-14
<b>Original CE Mark Date:</b>	See attached Product List
<b>Conformity Assessment:</b>	EU MDR 2017/745, Annex IX
<b>Device Photograph:</b>	Not Applicable per Regulation (EU) 2017/745, Annex IV, Number 4.



## MDR Declaration of Conformity

The products in the attached Declaration of Conformity Product List are approved under EC Certificate G70 014607 0257.

### Declaration of Conformity Product List for the Implantable Cardioverter Defibrillators

Model Number	Description	Product Trade Name	EMDN Code	GMDN Code	Original CE Mark Date	Basic UDI	UDI-DI (GTIN)
CD1233-40	ICD	Fortify™ VR	J010501	35852	29-Jan-2010	5415067HVD0002GV	05414734503457
CD1233-40Q	ICD		J010501	35852	29-Jan-2010		05414734503464
CD2233-40	ICD	Fortify™ DR	J010502	37265	29-Jan-2010		05414734503518
CD2233-40Q	ICD		J010502	37265	29-Jan-2010		05414734503525
CD1377-36C	ICD	Ellipse™ VR	J010501	35852	18-Dec-2012		05414734507622
CD1377-36Q	ICD		J010501	35852	15-May2015		05414734507653
CD1377-36QC	ICD		J010501	35852	15-May2015		05414734507646
CD2377-36C	ICD	Ellipse™ DR	J010502	37265	18-Dec-2012		05414734507509
CD2377-36QC	ICD		J010502	37265	15-May2015		05414734507523
CD1359-40	ICD	Fortify Assura™ VR	J010501	35852	18-Dec-2012		05414734507998
CD1359-40C	ICD		J010501	35852	18-Dec-2012		05414734507981
CD1359-40Q	ICD		J010501	35852	14-Jul-2015		05414734508018
CD1359-40QC	ICD		J010501	35852	14-Jul-2015		05414734508001
CD2359-40	ICD	Fortify Assura™ DR	J010502	37265	18-Dec-2012		05414734508117
CD2359-40C	ICD		J010502	37265	18-Dec-2012		05414734508100
CD2359-40Q	ICD		J010502	37265	14-Jul-2015		05414734508131
CD2359-40QC	ICD		J010502	37265	14-Jul-2015	05414734508124	
CD3235-40	CRT-D	Unify™	J010503	47270	29-Jan-2010	5415067HVD0001GT	05414734503556
CD3235-40Q	CRT-D		J010503	47270	29-Jan-2010		05414734503563
CD3251-40	CRT-D	Unify Quadra™	J010503	47270	15-Mar-2011		05414734504553
CD3251-40Q	CRT-D		J010503	47270	15-Mar-2011		05414734504560
CD3361-40	CRT-D	Unify Assura™	J010503	47270	18-Dec-2012		05414734508230
CD3361-40C	CRT-D		J010503	47270	18-Dec-2012		05414734508223
CD3361-40Q	CRT-D		J010503	47270	18-Dec-2012		05414734508254
CD3361-40QC	CRT-D		J010503	47270	18-Dec-2012		05414734508247
CD3367-40C	CRT-D	Quadra Assura™	J010503	47270	18-Dec-2012		05414734508308
CD3367-40QC	CRT-D		J010503	47270	13-Oct-2015		05414734508322
CD3371-40	CRT-D	Quadra Assura MP™	J010503	47270	18-Dec-2012		05414734508391
CD3371-40C	CRT-D		J010503	47270	18-Dec-2012		05414734508384
CD3371-40Q	CRT-D		J010503	47270	13-Oct-2015		05414734508414
CD3371-40QC	CRT-D		J010503	47270	13-Oct-2015		05414734508407

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 88136 MDR Declaration of Conformity Template Rev G

Page 4 of 4

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Abbott Medical  
15900 Valley View Court  
Sylmar CA 91342  
USA  
Tel: (408) 522-6464  
Fax: (818) 364-5814

0068163 Rev. A

## Declaration of Conformity

<b>Manufacturer:</b>	Abbott Medical
<b>Manufacturer SRN:</b>	US-MF-000010383
<b>Address:</b>	15900 Valley View Court Sylmar, CA 91342 USA
<b>Manufacturing Sites:</b>	Abbott Medical 15900 Valley View Court Sylmar, CA 91342
	Abbott Medical Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA
<b>European Authorized Representative:</b>	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, BELGIUM
<b>European Authorized Representative SRN:</b>	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

<b>Device Names:</b>	Insertable Cardiac Monitor, Patient Mobile Applications
<b>Product Trade Names:</b>	Jot Dx™; myMerlin™ mobile apps – Android and iOS
<b>Model Numbers:</b>	DM4500, APP1000 (Android), APP1001 (iOS)

<b>Signature:</b>  Colleen Canan Divisional Vice President, Global Regulatory Affairs, Cardiac Rhythm Management	Digitally signed by CANANCX Date: 2023.03.09 13:18:27 -08'00'  _____ March 9, 2023 Issue Date  On behalf of Abbott Medical, signed at Sylmar, California, USA
---	---



## Declaration of Conformity

<b>Intended Purpose:</b>	<p>The Jot Dx™ ICM is intended to help physicians and clinicians monitor, diagnose, and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.</p> <p>The myMerlin™ mobile application is intended for people who have a Jot Dx ICM or Confirm Rx ICM and access to a mobile device. The app allows the patient to activate recordings in the implanted device and wirelessly transmit data for physician and clinician review.</p>
<b>Risk Classification:</b>	<ul style="list-style-type: none"> <li>• Jot Dx™ ICM DM4500: Class III per EU MDR 2017/745 Annex VIII</li> <li>• myMerlin™ APP1000, APP1001: Class III per EU MDR 2017/745 Annex VIII</li> </ul>
<b>Risk Classification Rationale:</b>	<ul style="list-style-type: none"> <li>• Jot Dx™ ICM DM4500: Class III as per EU MDR 2017/745, Annex VIII, Rule 8, as a long term, surgically invasive, active implantable medical device.</li> <li>• myMerlin™ APP1000 and APP1001: Class III as per EU MDR 2017/745, Annex VIII, Rule 11 - Software intended to provide information which is used to make decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause death or an irreversible deterioration of a person's state of health, in which case it is in Class III.</li> </ul>
<b>EMDN Codes:</b>	DM4500: J010201 APP1000, APP1001: J01900282
<b>GMDN Codes:</b>	DM4500: 47804 APP1000, APP1001: 47805
<b>Basic UDI-DI:</b>	5415067CMD0002AK

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1



Abbott Medical  
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Sylmar CA 91342  
USA  
Tel: (408) 522-6464  
Fax: (818) 364-5814

0068163 Rev. A

## Declaration of Conformity

<b>Common Specifications Applied:</b>	Not Applicable. No common specifications are available for this type of device
<b>Notified Body:</b>	TÜV SÜD Product Service GmbH Ridlerstraße, 65, 80339 Munich, Germany  NB#0123
<b>Supporting Certificate(s):</b>	Technical Documentation Assessment Certificate Number: G70 014607 0259 Rev. 00  EU Quality Management System Certificate: G12 014607 0255 Rev. 01
<b>Original CE Mark Date:</b>	2022-11-15
<b>Conformity Assessment:</b>	Annex IX

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Page 3 of 3

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**SJM Declaration of Conformity  
Implantable Pacemakers  
ATTACHMENT TO DECLARATION OF CONFORMITY**

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

**Manufacturer Address:** *St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court  
Sylmar, CA 91342*

**European Representative:** *St. Jude Medical Coordination Center BVBA  
The Corporate Village  
Da Vincilaan 11 Box F1  
1935 Zaventem, Belgium*

**Product Type:** *Implantable Pacemakers*

**Product Name(s):** *See Attachment*

**Model Number(s):** *See Attachment*

**Classification:** *AIMD*

**GMDN Code(s):** *See Attachment*

**Original CE Mark Date:** *See Attachment*

**(FQA or EC as appropriate) Certificate No and expiration date:** *EC  
Certification No: I7 014607 0234 Rev. 01  
Expiration Date: 2024-05-26*

*FQA  
Certificate No: I1 014607 0211 Rev. 01  
Expiration Date: 2024-05-26*

*EN ISO 13485:2016  
Certificate No: Q5 014607 0231 Rev. 00  
Expiration Date: 2022-03-31*

**Signature:**

  
Kathy Berg  
Sr. Manager Regulatory Affairs

  
Issue Date

**SJM Declaration of Conformity  
Implantable Pacemakers  
ATTACHMENT TO DECLARATION OF CONFORMITY****Applicable Quality System Standards:**

Fulfills the requirements of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC and corresponding national legislation.

Fulfills applicable requirements including CE marking and the Essential Requirements of the AIMDD, 90/385/EEC and corresponding national legislation.

**Notified Body:**

TÜV SÜD Product Service GmbH Zertifizierstelle  
Ridlerstraße 65, 80339, München, Germany

**Notified Body Number:**

0123

**Manufacturing Facilities:**

*St. Jude Medical Cardiac Rhythm Management Division  
15900 Valley View Court Sylmar, CA 91342 USA*

*St. Jude Medical Puerto Rico LLC  
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park,  
Arecibo PR 00612, USA*

*St. Jude Medical Operations (M) Sdn. Bhd  
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas  
Industrial Zone, 11900 Penang, MALAYSIA*

**Signature:**

  
Kathy Berg  
Sr. Manager Regulatory Affairs

  
Issue Date

**SJM Declaration of Conformity**  
**Implantable Pacemakers**  
**ATTACHMENT TO DECLARATION OF CONFORMITY**

The following product(s) is/are approved under EC-certificate number **I7 014607 0234 Rev. 01:**

Product Name	Model No.	GMDN Codes	First Date of CE Marking
Microny™ II SR+	2525T	47267	1999-9-17
Zephyr™ XL DR	5826	47265	2006-5-9
Zephyr™ DR	5820	47265	2006-5-9
Zephyr™ SR	5620	47267	2006-5-9
Zephyr™ XL SR	5626	47267	2007-6-13
Assurity™	PM1240	47267	2013-3-7
Assurity™	PM2240	47265	2013-3-7
Endurity™	PM1160	47267	2013-3-7
Endurity™	PM2160	47265	2013-3-7
Allure™	PM3120	47263	2013-3-7
Allure™ RF	PM3222	47263	2013-3-7
Allure Quadra™ RF	PM3242	47263	2013-3-7
Quadra Allure MP™ RF	PM3262	47263	2014-7-31
Assurity MRI™	PM1272 (MR Conditional)	47267	2014-12-18
Assurity MRI™	PM2272 (MR Conditional)	47265	2014-12-18
Endurity MRI™	PM1172 (MR Conditional)	47267	2014-12-18
Endurity MRI™	PM2172 (MR Conditional)	47265	2014-12-18
Endurity™	PM1162 (MR Conditional)	47267	2014-12-18
Endurity™	PM2162 (MR Conditional)	47265	2014-12-18
Endurity™ Core	PM1140 (MR Conditional)	47267	2015-7-24
Endurity™ Core	PM2140 (MR Conditional)	47265	2015-7-24
Endurity™ Core	PM1152 (MR Conditional)	47267	2015-7-24
Endurity™ Core	PM2152 (MR Conditional)	47265	2015-7-24
Quadra Allure™	PM3542 (MR Conditional)	47263	2016-10-21
Quadra Allure MP™	PM3562 (MR Conditional)	47263	2016-10-21
Zenex™	PM1250	47267	2018-10-12
Zenex™	PM2250	47265	2018-10-12
Zenus™	PM1170	47267	2018-10-12
Zenus™	PM2170	47265	2018-10-12
Zenex MRI™	PM1282 (MR Conditional)	47267	2018-10-12

Signature:

  
 Kathy Berg  
 Sr. Manager Regulatory Affairs

  
 Issue Date



**SJM Declaration of Conformity  
Implantable Pacemakers  
ATTACHMENT TO DECLARATION OF CONFORMITY**

Product Name	Model No.	GMDN Codes	First Date of CE Marking
Zenex MRI™	PM2282 (MR Conditional)	47265	2018-10-12
Zenus MRI™	PM1182 (MR Conditional)	47267	2018-10-12
Zenus MRI™	PM2182 (MR Conditional)	47265	2018-10-12
Verity™ ADx XL VDR	5456	47265	2003-8-22

Signature:

Kathy Berg  
Sr. Manager Regulatory Affairs

Issue Date



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Product Service

## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
 (Implantable Class IIb Devices and Class III Devices)

**No. G70 014607 0257 Rev. 00**

<b>Manufacturer:</b>	<b>Abbott Medical</b> 15900 Valley View Court Sylmar CA 91342 USA
<b>SRN Manufacturer:</b>	US-MF-000010383
<b>Authorized Representative:</b>	Abbott Medical The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G70\\_014607\\_0257\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G70_014607_0257_Rev.00)

<b>Report No.:</b>	713224396
<b>Valid from:</b>	2022-08-15
<b>Valid until:</b>	2027-08-14

Christoph Dicks  
 Head of Certification/Notified Body

**Issue date:** 2022-08-15



## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
 (Implantable Class IIb Devices and Class III Devices)

**No. G70 014607 0257 Rev. 00**

**Classification:** III  
**Device Group:** J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS  
**Basic UDI-DI:** 5415067HVD0002GV  
**Intended Purpose:** The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, ICD devices can detect and treat

- chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle
- various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium

**Device(s):** Fortify™ VR, Fortify Assura™ VR, Ellipse™ VR. For device variants/models and parameters please see model list no. 1 at the end of the certificate.

**Classification:** III  
**Device Group:** J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS  
**Basic UDI-DI:** 5415067HVD0002GV  
**Intended Purpose:** The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, ICD devices can detect and treat

- chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle
- various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.

**Device(s):** Fortify™ DR, Fortify Assura™ DR, Ellipse™ DR. For device variants/models and parameters please see model list no. 2 at the end of the certificate.



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Product Service

## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
(Implantable Class IIb Devices and Class III Devices)

**No. G70 014607 0257 Rev. 00**

<b>Classification:</b>	III
<b>Device Group:</b>	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
<b>Basic UDI-DI:</b>	5415067HVD0001GT
<b>Intended Purpose:</b>	The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, these devices can detect and treat chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium. CRT-D devices sense cardiac activity and provide pacing to resynchronize the right and left ventricles.
<b>Device(s):</b>	Unify™, Unify Quadra™, Quadra Assura™, Quadra Assura MP™, Unify Assura™. For device variants/models and parameters please see model list no. 3 at the end of the certificate.

**The validity of this certificate depends on conditions and/or is limited to the following:** /.

### List no. 1:

Ellipse™ VR / CD1377-36C  
Ellipse™ VR / CD1377-36Q  
Ellipse™ VR / CD1377-36QC  
Fortify™ VR / CD1233-40  
Fortify™ VR / CD1233-40Q  
Fortify Assura™ VR / CD1359-40  
Fortify Assura™ VR / CD1359-40C  
Fortify Assura™ VR / CD1359-40Q  
Fortify Assura™ VR / CD1359-40QC

### List no. 2:

Ellipse™ DR / CD2377-36C  
Ellipse™ DR / CD2377-36QC  
Fortify™ DR / CD2233-40  
Fortify™ DR / CD2233-40Q  
Fortify Assura™ DR / CD2359-40  
Fortify Assura™ DR / CD2359-40C  
Fortify Assura™ DR / CD2359-40Q  
Fortify Assura™ DR / CD2359-40QC



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Product Service

## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
(Implantable Class IIb Devices and Class III Devices)

**No. G70 014607 0257 Rev. 00**

### List no. 3:

Unify™ / CD3235-40  
Unify™ / CD3235-40Q  
Unify Quadra™ / CD3251-40  
Unify Quadra™ / CD3251-40Q  
Unify Assura™ / CD3361-40  
Unify Assura™ / CD3361-40C  
Unify Assura™ / CD3361-40Q  
Unify Assura™ / CD3361-40QC  
Quadra Assura™ / CD3367-40C  
Quadra Assura™ / CD3367-40QC  
Quadra Assura MP™ / CD3371-40  
Quadra Assura MP™ / CD3371-40C  
Quadra Assura MP™ / CD3371-40Q  
Quadra Assura MP™ / CD3371-40QC



# 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](http://www.dekra-product-safety.com) Company registration 09085396



# ADDENDUM

Belonging to certificate: 2181711DE02

217

## 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

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# ADDENDUM

Belonging to certificate: 2181711DE02

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## EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

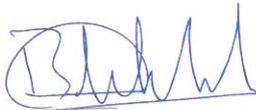
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619266 Singapore  
Singapore

### PULMONARY ARTERY MONITORING CATHETER – MODEL REFERENCES

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

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: 2181711DE02

## 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

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# ADDENDUM

Belonging to certificate: 2181711DE02

5/7

## EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

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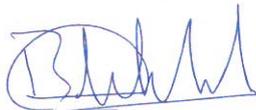
**Bioptimal International PTE. LTD.**

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619266 Singapore  
Singapore

### BIOTRAY – MODEL REFERENCES

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

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B.T.M. Holtus  
Managing Director



J.A. van Vugt  
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# ADDENDUM

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## EC DESIGN-EXAMINATION MEDICAL DEVICES

Thermodilution Catheter, Pulmonary Artery Monitoring Catheter, Biotray

Issued to:

### **Bioptimal International PTE. LTD.**

**36 Jalan Tukang  
619266 Singapore  
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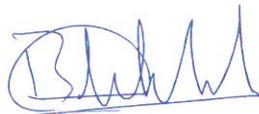
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BIOTRAY TD2502  
BIOTRAY TD2502-110  
BIOTRAY TD2602  
BIOTRAY TD2702  
BIOTRAY TD2603  
BIOTRAY TD2703

---

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

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

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# ADDENDUM

Belonging to certificate: 2181711DE02

717

## 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

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## DECLARATION OF CONFORMITY

We

Bioptimal International Pte. Ltd.  
36 Jalan Tukang  
Singapore 619266

declare on our own responsibility that the medical device:

### **Thermodilution Catheter/ Pulmonary Artery Monitoring Catheter/ Biotray**

(Catalogue number: see Annexes 1, 2, 3)

meets all applicable requirements of the Medical Device Directive 93/42/EEC Annex II, section 4 and Annex II, section 3, including the amendments of the Medical Device Directive 2007/47/EC; and RoHS Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

<b>Classification</b>	Class III based on Annex IX, Rule 7 of the Medical Device Directive 93/42/EEC
<b>Applied standards</b>	Refer to Annex 4 for the standard list
<b>Notified body</b>	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem The Netherlands
<b>EC Notified Body Identification Number</b>	0344
<b>Conformity assessment procedures</b>	MDD, Annex II, Section 3, CE Marking of Conformity certificate: - <b>2181711CE01</b> issued on 15 July 2015, reissued and revised on 30 March 2020

**BIOPTIMAL INTERNATIONAL PTE. LTD.** (Co. Reg. No. 198904428G)  
Registered Address: 36 Jalan Tukang, Singapore 619266  
Tel: 6213 5777 Fax: 6213 5737  
[www.bioptimalg.com](http://www.bioptimalg.com)



MDD Annex II, Section 4, EC Design Examination certificate:  
- **2181711DE02** issued on 15 July 2015, reissued on 1<sup>st</sup>  
April 2020

**Representative in EU**

Shanghai International Holding Corp. GmbH  
Eiffestrasse 80,  
20537 Hamburg,  
Germany

**Place** Bioptimal International Pte. Ltd.  
**Date** 1<sup>st</sup> April 2020  
**Name** Jane Chen Jiayan  
**Title** Manager, Quality Assurance & Regulatory Affairs  
**Signature**

A handwritten signature in blue ink, appearing to be 'Jc' or similar initials.





## Annex 1

### Thermodilution Catheter – Model references

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

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

### Pulmonary Artery Monitoring Catheter – Model references

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

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### Annex 3

#### 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	
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

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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



## **Annex 4**

**Standard list (ST-0049)**



## Addendum

### History Log – Lot and Time Range

#### Thermodilution Catheter

First Release Date	Initial lot number and succeeding
26 Nov 2015	H151000017

#### Pulmonary Artery Monitoring Catheter

First Release Date	Initial lot number and succeeding
26 Nov 2015	H151000004

#### Biotray

First Release Date	Initial lot number and succeeding
18 Jan 2016	H151100222



The Standards listed below were taken into consideration in the manufacture of Thermodilution Catheter/  
 Pulmonary Artery Monitoring Catheter/ Biotray.

**1. STANDARDS FOR COMPLIANCE**

European Directive	Document
Council Directive 93/42/EEC	Medical Devices
2007/47/EC	Amends Directive 93/42/EEC
2011/65/EC	Restriction of the use of certain hazardous substances in electrical and electronic equipment, RoHS Directive 2011/65/EC

Guidance	Document
MEDDEV 2.7/1 rev.4: 2016	Clinical evaluation: Guide for manufacturers and notified bodies
MEDDEV 2.12/1 rev.8: 2013	Medical devices vigilance system
MEDDEV 2.12/2 rev 2: 2012	Post Market Clinical Follow-Up Studies

Harmonised standards under Directive 93/42/EEC for Medical Devices	Title
EN 1041:2008	Information supplied by the manufacturer of medical devices
BS EN ISO 10555-1:2013	Sterile, single-use intravascular catheters - Part 1: General requirements
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems



Standards List  
**Thermodilution Catheter/  
Pulmonary Artery Monitoring Catheter/  
Biotray**

Document No.: ST-0049  
Revision: 09  
ECO #: 20547  
Effective Date: 23 Apr 2021  
Page: 2 of 3

Harmonised standards under Directive 93/42/EEC for Medical Devices	Title
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 62366:2015	Medical devices - Application of usability engineering to medical devices
EN 556-1:2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated as “STERILE” – Part 1: Requirements for terminally sterilized medical devices
EN 15986:2011	Symbol for use in the labeling of medical devices – Requirements for labeling of medical devices containing phthalates
Other European Standards	Title
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied



**2. STANDARDS FOR REFERENCE PURPOSES ONLY**

Other Standards	Document
EN 60601-1:2006	Medical electrical equipment- Part 1: General requirements for basic safety and essential performance
BS EN ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires
ISO 2859-1:1999 (EN)	Sampling procedures for inspection by attributes - Part 1 : Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications- Part 7: Connectors for intravascular or hypodermic applications
EN ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements

ASTM Standards	Document
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
ASTM D747	Standard Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam
ASTM F640	Standard Test Methods for Determining Radiopacity for Medical Use

Revision	Release Date	Description	Author
01	31-Mar-2015	Initial Release under ST-0049.	Samantha Ong
02	23-Feb-2016	<ul style="list-style-type: none"> <li>• Update of standard revisions, rearranging of standards to appropriate sections</li> <li>• Reduced number of sections to Standards for Compliance and Standards For Reference Purposes Only</li> </ul>	Roy Tay
03	29-Apr-2016	Update to include only relevant standards	Muhammad Amsyar
04	05-Jul-2016	Included EN 62366:2008 in list of standards	Muhammad Amsyar
05	17-Mar-2017	Update to include relevant standards for CE renewal	Hoo Hsing Yi
06	23 Jan 2018	Updated to relevant standards	Lor Yen Yin
07	23 Oct 2019	Updated to relevant standards	Lor Yen Yin
08	21 Sep 2020	Updated to relevant standards	Iyris Foo Chuk Kuan
09	23 Apr 2021	Updated to relevant standards	Wan Wei Khang