

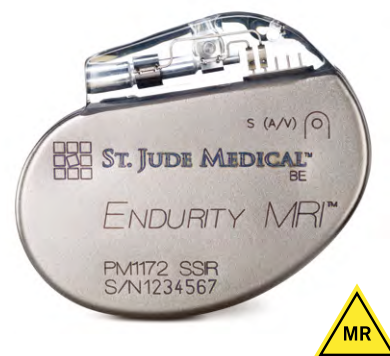
## Endurity MRI™

## Single-Chamber Pacemaker

## Product Highlights - Pacemaker

The Endurity MRI pacemaker is designed to allow patients to undergo MRI scans:

- When combined with the Tendril MRI™ LPA1200M lead, the MRI-ready device:
  - Allows full-body, MRI scans
  - Permits a maximum whole body averaged specific absorption rate (SAR) of 4 Watts per kilogram (W/kg)
- In patients who have Tendril™ 2088TC or IsoFlex™ Optim™ 1944/1948 Leads, the MRI Ready device:
  - Allows MRI scans\*
  - Permits a maximum whole body averaged specific absorption rate (SAR) of 2 Watts per kilogram (W/kg)
- Physician preferred size and physiologic shape minimize pocket size
- Outstanding longevity provides 14,4 years of service life,<sup>7</sup> which is supported by a 10-year warranty<sup>8</sup>
- AutoCapture™ pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation. The AutoCapture pacing system automatically delivers a 5,0 V backup safety pulse when noncapture is detected, and it may be programmed to either a bipolar or unipolar configuration
- A suite of state-of-the-art features—such as automaticity, Ventricular AutoCapture™ pacing system and SenseAbility™ technology—are designed to deliver optimal therapy for patients at implant and throughout their lives
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options
- 6-month ERI-EOL interval
- An optional, easy-to-use hand-held device (SJM MRI Activator™ device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency



\*See MRI Conditional Parameters

## Ordering Information - MRI-Ready Pacing System

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector	
PM1172	Endurity MRI Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1	
Model Number	Description	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
LPA1200M	Tendril MRI Pacing Leads	Optim™	Ext/Ret helix	8	IS-1 bipolar	46, 52, 58
2088TC	Tendril STS Pacing Leads	Optim™	Ext/Ret helix	6	IS-1 bipolar	46, 52, 58
1944 (J-shaped)	IsoFlex Optim Pacing Leads	Optim™	Tines	7	IS-1 bipolar	46,52
1948 (Straight)	IsoFlex Optim Pacing Leads	Optim™	Tines	7	IS-1 bipolar	52, 58

**Indications:** Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. **Rate-Modulated Pacing** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. **Atrial Pacing** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. **Ventricular Pacing** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

**Contraindications:** **Single-chamber pulse generators** are contraindicated in patients with an implanted cardioverter-defibrillator. **Rate-Adaptive Pacing** may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. **Single-Chamber Ventricular Demand Pacing** is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. **Single-Chamber Atrial Pacing** is relatively contraindicated in patients who have demonstrated compromise of AV conduction. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

**Potential Adverse Events:** The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

# Endurity MRI™

## Single-Chamber Pacemaker

### Product Specifications - Pacemaker

#### PHYSICAL SPECIFICATIONS

<b>Model</b>	<b>PM1172</b>
Telemetry	Inductive
Dimensions (mm)	41 x 50 x 6
Weight (g)	19
Volume (cc)	9.7
Connector	IS-1

#### Remote Monitoring

Compatible with Merlin@home™ Transmitter

#### PARAMETER SETTINGS

##### Rate/Timing

Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470 <sup>2</sup>
Base Rate (min <sup>-1</sup> )	30-130 in steps of 5; 140-170 in steps of 10
Mode	V00(R); VVI(R); VVT(R); Pacing Off A00(R); AA1(R); AAT(R)
Hysteresis Rate (min <sup>-1</sup> )	Off; 30 <sup>2</sup> -150 in steps of 5
Search Interval (min <sup>-1</sup> )	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min <sup>-1</sup> )	Off; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30; Same as Base Rate
Intervention Duration (min)	1-10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min <sup>-1</sup> )	Off; 30-150; in steps of 5
Rate Responsive VREF	Off; Low; Medium; High
Shortest VREF	125-475 in steps of 25

##### Output/Sensing

ACap™ Confirm <sup>3</sup>	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5.0 <sup>3</sup>
Search Interval (hours)	8; 24
A or V Pulse Amplitude (V)	0.25-4.0 in steps of 0.25; 4.5-7.5 in steps of 0.5
A or V Pulse Width (ms)	0.05; 0.1-1.5 in steps of 0.1
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	0.1-0.4 <sup>10</sup> in steps of 0.1; 0.5; 0.75-2.0 in steps of 0.25; 2.5-4.0 in steps of 0.5; 5.0 <sup>4</sup>
V Sensitivity (mV)	0.5-5.0 in steps of 0.5; 6-10 in steps of 1.0; 12.5 <sup>4</sup>
Ventricular AutoCapture™	
Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5.0 <sup>3</sup>
Search Interval (hours)	8; 24
SenseAbility™ Technology	Off; On (Automatic Sensitivity Control adjustment for atrial or ventricular events)
A Max Sensitivity (mV)	0.2-1.0 in steps of 0.1
V Max Sensitivity (mV)	0.2-2.0 in steps of 0.1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62.5; 75; 100% (Atrial Post-Pace) 0.2-3.0 in steps of 0.1 mV (Ventricular Post-Pace) Auto; 0.2-3.0 in steps of 0.1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220

##### MRI Settings

MRI Mode	A00; V00; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
MRI Atrial Pulse Configuration	Bipolar
MRI Atrial Pulse Amplitude	5.0 V; 7.5 V
MRI Atrial Pulse Width	1.0 ms
MRI RV Pulse Configuration	Bipolar
MRI RV Pulse Amplitude	5.0 V; 7.5 V
MRI RV Pulse Width	1.0 ms

Customer Support: 46-8-474-4756



**Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

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#### MRI Conditional Parameters

Lead	Lead Lengths	Scan Exclusion Zone
Tendril MRI LPA1200M Lead	46, 52, 58 cm	No scan exclusion zone
Tendril 2088TC Lead	46, 52, 58 cm	Isocenter must be inferior to L4 or 10 cm superior to C1
IsoFlex 1944 Lead	46, 52 cm	Isocenter must be inferior to L4 or superior to C1
IsoFlex 1948 Lead	52, 58 cm	Isocenter must be inferior to L4 or superior to C1

Lead	Lead Lengths	Magnet	SAR	
Tendril MRI LPA1200M Lead	46, 52, 58 cm	1.5T	≤ 4 W/kg	
Tendril 2088TC Lead	46, 52, 58 cm	1.5T	≤ 2 W/kg	
IsoFlex 1944 Lead	46, 52 cm	1.5T	≤ 2 W/kg	
IsoFlex 1948 Lead	52, 58 cm	1.5T	≤ 2 W/kg	

#### AF Management<sup>4</sup>

AF Suppression™ Algorithm	Off; On (Atrial implants only)
Lower Rate Overdrive (min <sup>-1</sup> )	10 <sup>3</sup>
Upper Rate Overdrive (min <sup>-1</sup> )	5 <sup>3</sup>
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8;12 <sup>3</sup>
Maximum AF Suppression Rate (min <sup>-1</sup> )	80-150 in steps of 5; 160-180 in steps of 10
Atrial Tachycardia Detection Rate (min <sup>-1</sup> )	110-200 in steps of 10; 225-300 in steps of 25

#### Rate-Modulated Parameters

Maximum Sensor Rate (min <sup>-1</sup> )	80-150 in steps of 5; 160-180 in steps of 10
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1
Threshold	Auto (-0.5); Auto (+0.0); Auto (+0.5); Auto (+1.0); Auto (+1.5); Auto (+2.0); 1-7 in steps of 0.5

#### Stored Electrograms

Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Magnet Response	Off; Low; High
High Ventricular Rate Rate (min <sup>-1</sup> )	Off; Low; High
No. of Consecutive Cycles	125-300 in steps of 25
Advanced Hysteresis	2; 3; 4; 5; 10; 15; 20
Noise Reversion	Off; Low; High

High Ventricular Rate can alternately be High Atrial Rate; they use the same sub-parameters.

#### Other

Lead Monitoring	Monitor; Auto Polarity Switch
V Low Impedance Limit (Ω)	100-500 in steps of 25
V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Atrial limits apply when implanted in the atrium.	
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
NIPS Options	
Stimulation Chamber	Atrial or Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	2-25 in steps of 1
S1; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; R (or P) Wave; V (or A) Threshold

- ± 0.5 cc
- Programming options dependent on pacing mode.
- The highest available setting for hysteresis rate will be 5 min<sup>-1</sup> below the programmed base rate.
- Sensitivity is with respect to a 20 ms haversine test signal.
- This parameter is not programmable.
- S1 Burst Cycle is applied at the preprogrammed S1 cycle length.
- A.V = 2.5 V @ 0.4 ms; 500 ohms; 100% VVI pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMS ON
- Terms and conditions apply; refer to the warranty for details
- Atrial Implants Only
- Values 0.1-0.4 not available in a unipolar sense configuration.

# Tendril™ STS

## Pacing Lead



### Product Highlights - Pacing Lead

- The Tendril STS lead allows patients to undergo MRI scans when used in conjunction with a MRI Ready pacemaker from St. Jude Medical
  - Allows MRI scans (See Parameter Settings for scan exclusion zone)
  - Permits a maximum whole body averaged specific absorption rate (SAR) of 2 watts per kilogram (W/kg)
- Soft silicone tip offers more compliance and less tip pressure at the lead tip-endocardium interface
- Small diameter lead offers improved ease of venous passage, reduced risk of venous thrombosis or rib-clavicle crush and ability to accommodate additional leads more easily
- Optim™ lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Titanium nitride (TiN) fractal coating on the tip and ring electrodes is designed to promote precise sensing and to provide improved contact with the myocardium
- Lubricious Fast-Pass™ coating facilitates lead insertion through the introducer and veins to ease implantation
- Fits through a 6 F introducer

### Ordering Information - MRI-Ready Pacing System

Model Number	Description	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
2088TC	Tendril™ STS Pacing Lead	Optim™	Ext/Ret helix	6	IS-1 bipolar	46*; 52*; 58*; 65; 100

\* Indicates lead lengths that are MRI conditional with a scan exclusion zone.

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1140	Endurity™ Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2140	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1152	Endurity Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2152	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1162	Endurity Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2162	Endurity Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1172	Endurity MRI™ Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2172	Endurity MRI Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1272	Assurity MRI™ Pacemaker	47 x 50 x 6	20	10,4 (± 0,5)	IS-1
PM2272	Assurity MRI Pacemaker	47 x 50 x 6	20	10,4 (± 0,5)	IS-1

**Indications:** Tendril™ STS lead is designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS lead may be indicated for patients where permanent fixation of passive leads is suspected to be unstable.

In atrial applications, the use of screw-in leads such as Tendril STS lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

**Contraindications:** Tendril STS lead is contraindicated: in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

**Adverse Events:** Potential complications associated with the use of Tendril STS lead are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

## Tendril™ STS

## Pacing Lead

## Product Specifications - Pacing Leads

## PHYSICAL SPECIFICATIONS

Model	2088TC
Minimum Introducer Size	6 F
Type of Lead	Active-fixation, bipolar, steroid-eluting, endocardial, pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	46; 52; 58; 65; 100 cm
Fixation Mechanism	Extendable/Retractable helix
Typical Number of Rotations for Helix Extension	6-11 (straight stylet)
Lead Body Diameter	1.9 mm (max)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active titanium-nitride-coated Pt/Ir helix (2,0 mm extension)
Tip Electrode Surface Area	6.9 mm <sup>2</sup>
Ring Electrode (Anode)	Titanium-nitride-coated Pt/Ir
Ring Electrode Surface Area	16 mm <sup>2</sup>
Mapping	Capable with titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/Outer Conductor	MP35N™* coil
Inner Insulation	Silicone rubber
Outer Insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating

## In Pack

Straight stylets	1 x-soft in lead; 1 x-soft; 1 soft
J-curved stylets	2 soft
Helix extension/retraction clip-on tools	2 clip-on tools

## Accessory Kits

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DS06002 with appropriate length designation	46; 52; 58; 65; 100 cm	1 fixation tool; 1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
	DS06003 with appropriate length designation	46; 52; 58; 65; 100 cm	1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46; 52; 58; 65 cm	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
	1292 with appropriate length designation	46; 52; 58; 65 cm	

## MRI Conditional Parameters

Magnet strength: 1.5 Tesla

SAR: ≤ 2 W/kg

Scan region: Isocenter must be inferior to L4 or 10 cm superior to C1



\*MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

**Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

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## 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 0258 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\\_0258\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G70_014607_0258_Rev.00)

**Report No.:** 713261279

**Valid from:** 2023-09-18

**Valid until:** 2028-09-17

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2023-09-18



## 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 0258 Rev. 00**

<b>Classification:</b>	Class III
<b>Device Group:</b>	J01010101 - IMPLANTABLE SINGLE CHAMBER PACEMAKERS (SC)
<b>Basic UDI-DI:</b>	5415067LVD0001JX
<b>Intended Purpose:</b>	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
<b>Device(s):</b>	Endurity™ Core PM1140
<b>Classification:</b>	Class III
<b>Device Group:</b>	J01010102 - IMPLANTABLE SINGLE CHAMBER PACEMAKERS WITH SENSOR (SR)
<b>Basic UDI-DI:</b>	5415067LVD0001JX
<b>Intended Purpose:</b>	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
<b>Device(s):</b>	Endurity™ Core PM1152 Endurity™ PM1162 Endurity MRI™ PM1172 Assurity MRI™ PM1272 Zenex MRI™ PM1282 Zenus MRI™ PM1182
<b>Classification:</b>	Class III
<b>Device Group:</b>	J01010301 - IMPLANTABLE DUAL CHAMBER PACEMAKERS (DC)
<b>Basic UDI-DI:</b>	5415067LVD0001JX
<b>Intended Purpose:</b>	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
<b>Device(s):</b>	Endurity™ Core PM2140



## 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 0258 Rev. 00**

**Classification:** Class III  
**Device Group:** J01010302 - IMPLANTABLE DUAL CHAMBER PACEMAKERS WITH SENSOR (DR)  
**Basic UDI-DI:** 5415067LVD0001JX  
**Intended Purpose:** The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.  
**Device(s):** Endurity™ Core PM2152  
 Endurity™ PM2162  
 Endurity MRI™ PM2172  
 Assurity MRI™ PM2272  
 Zenex MRI™ PM2282  
 Zenus MRI™ PM2182

**Classification:** Class III  
**Device Group:** J01010401 - IMPLANTABLE TRIPLE CHAMBER PACEMAKERS FOR CARDIAC RESYNCHRONIZATION (TR)  
**Basic UDI-DI:** 5415067LVD0002JZ  
**Intended Purpose:** The CRT-P devices when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the ventricle(s) and/or right atrium. The CRT-P devices are intended to resynchronize the right and left ventricles via biventricular pacing.  
**Device(s):** Allure™ RF PM3222  
 Quadra Allure™ PM3542  
 Quadra Allure MP™ PM3562  
 Quadra Allure MP™ RF PM3262

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

**Revision History:**

Rev.	Dated	Report	Description
00	2023-09-18	713261279	Initial issuance



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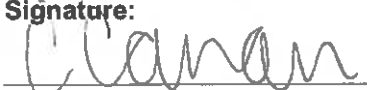
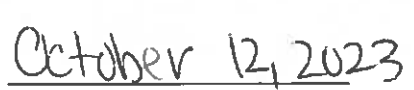
00114571 Rev. A

## Declaration of Conformity

<b>Manufacturer:</b>	Abbott Medical
<b>Manufacturer SRN:</b>	US-MF-000010383
<b>Address:</b>	15900 Valley View Court Sylmar, California 91342 United States of America
<b>Manufacturing Site(s):</b>	Abbott Medical 15900 Valley View Court Sylmar, California 91342 United States of America  Abbott Medical Lot A Interior - #2 Rd Km. 67.5 Santana Industrial Park, Arecibo PR United States of America  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 Trade Name(s):</b>	See attached Product List
<b>Model Number(s):</b>	See attached Product List
<b>Intended Purpose:</b>	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat

<b>Signature:</b>  Colleen Canan Divisional Vice President Regulatory Affairs	 Issue Date On behalf of Abbott Medical, signed at Sylmar, CA.
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## MDR Declaration of Conformity

	<p>chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.</p> <p>The CRT-P devices when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the ventricles and/or right atrium. The CRT-P devices are intended to resynchronize the right and left ventricles via biventricular pacing.</p> <p>The torque driver is intended to secure lead connectors and port plugs within the device header.</p>
<b>Risk Classification:</b>	<b>Class III</b> as per EU MDR 2017/745 per Annex VIII
<b>Risk Classification Rationale:</b>	Annex VIII, Rule 8, 6th Indent
<b>EMDN Code(s):</b>	See attached Product list.
<b>GMDN Code:</b>	See attached Product list.
<b>Basic UDI-DI:</b>	<p>Implantable Single and Dual Chamber Pacemakers: 5415067LVD0001JX</p> <p>Implantable Triple Chamber Pacemakers (CRT-P): 5415067LVD0002JZ</p>

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>Notified Body:</b>	<p>TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany</p> <p>ID Number: 0123</p>
<b>Supporting Certificate(s):</b>	<p>Technical Documentation Assessment Certificate Number: G70 014607 0258 Rev. 00 Expiration Date: 2028-09-17</p>

## MDR Declaration of Conformity

	EU Quality Management System Certificate: G12 014607 0255 Rev. 05 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

The products in the attached Declaration of Conformity Product List are approved under EC Certificate G70 014607 0258 Rev. 00.

### Declaration of Conformity Product List

Model No.	Product Trade Name	Original CE Mark Date	EMDN Code	GMDN Code	Basic UDI-DI
PM1140	Endurity™ Core	2015-07-24	J01010101	47267	5415067LVD0001JX
PM1152	Endurity™ Core		J01010101	47267	5415067LVD0001JX
PM2140	Endurity™ Core		J01010301	47265	5415067LVD0001JX
PM2152	Endurity™ Core		J01010301	47265	5415067LVD0001JX
PM1162	Endurity™	2014-12-18	J01010101	47267	5415067LVD0001JX
PM2162	Endurity™		J01010301	47265	5415067LVD0001JX
PM1172	Endurity MRI™		J01010101	47267	5415067LVD0001JX
PM2172	Endurity MRI™		J01010301	47265	5415067LVD0001JX
PM1272	Assurity MRI™	2018-10-12	J01010101	47267	5415067LVD0001JX
PM2272	Assurity MRI™		J01010301	47265	5415067LVD0001JX
PM2282	Zenex MRI™		J01010301	47265	5415067LVD0001JX
PM1282	Zenex MRI™		J01010101	47267	5415067LVD0001JX
PM2182	Zenus MRI™	2018-10-12	J01010301	47265	5415067LVD0001JX
PM1182	Zenus MRI™		J01010101	47267	5415067LVD0001JX
PM3222	Allure™ RF	2013-03-07	J01010401	47263	5415067LVD0002JZ
PM3542	Quadra Allure™	2016-10-21	J01010401	47263	5415067LVD0002JZ
PM3262	Quadra Allure MP™	2013-03-07	J01010401	47263	5415067LVD0002JZ
PM3562	Quadra Allure MP™	2016-10-21	J01010401	47263	5415067LVD0002JZ



# Certificate

No. Q5 014607 0231 Rev. 03

**Holder of Certificate:** **Abbott Medical**  
15900 Valley View Court  
Sylmar CA 91342  
USA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of Implantable Pulse Generators and Implantable Cardioverter Defibrillators, Implantable Leads for AIMDs, Programmers for AIMDs, Application Software (external), Cardiac Rhythm Management Device Accessories (adapters, stylets, guidewires, tools, etc.)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 014607 0231 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_014607_0231_Rev.03)

**Report No.:** 713237689

**Valid from:** 2022-08-12  
**Valid until:** 2025-03-31

**Date,** 2022-08-12

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 014607 0231 Rev. 03

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Abbott Medical  
15900 Valley View Court, Sylmar CA 91342, USA

Design and Development, Production and Distribution of  
Implantable Pulse Generators and Implantable Cardioverter  
Defibrillators, Implantable Monitoring and Recording Systems,  
Implantable Leads for AIMDs, Programmers for AIMDs,  
Application Software (external), Cardiac Rhythm Management  
Device, Accessories (adapters, stylets, guidewires, tools, etc)

Abbott Medical  
645 Almanor Avenue, Sunnyvale CA 94085, USA

Design and Development of Implantable Pulse Generators and  
Implantable Cardioverter Defibrillators, Implantable Monitoring and  
Recording Systems, Implantable Leads for AIMDs, Programmers  
for AIMDs, Application Software (external), Cardiac Rhythm  
Management Device Accessories (adapters, stylets, guidewires,  
tools, etc.); and returned product analysis of Implantable  
Cardioverter Defibrillators, Implantable Monitoring and Recording  
Systems and Cardiac Rhythm Management Device Accessories

# CERTIFICATE



This is to certify that



**SANTE**  
INTERNATIONAL S.A.

## SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2  
023961 Bucuresti  
Romania

has implemented and maintains a **Quality Management System**.

Scope:

Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

## ISO 9001 : 2015

Certificate registration no. 497269 QM15  
Valid from 2021-06-16  
Valid until 2024-06-15  
Date of certification 2021-06-16



### DQS GmbH

Markus Bleher  
Managing Director



**Annex to certificate  
Registration No. 497269 QM15**

**SANTE INTERNATIONAL S.A.**

Str. Mantuleasa nr. 33, Sector 2  
023961 Bucuresti  
Romania

**Location**

**Scope**

**075906  
Sante International SA  
Sos. Mihai Bravu nr. 7, bl. P37-P37A,  
sector 2  
021303 Bucuresti  
Romania**

Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.

**497270  
Sante International SA  
Str. Pupitrului, nr. 81,  
sect. 3  
033036 Bucuresti  
Romania**

Storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

**31050285  
Sante International SA  
Calea Ghirodei, nr. 36  
300327 Timisoara  
Romania**

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

**31050284  
Sante International SA  
Calea Dorobantilor, nr. 111  
400609 Cluj-Napoca  
Romania**

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

**31050283  
Sante International SA  
Str. Lascar Catargi, nr. 37  
700107 Iasi  
Romania**

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.