

Endurity MRI™

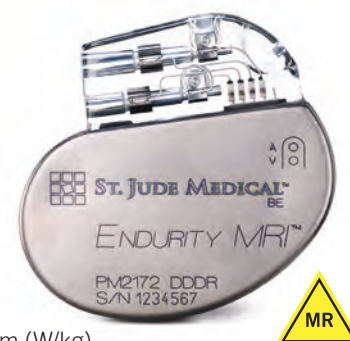
Dual-Chamber Pacemaker

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)
- When combined with 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 9,7 years of service life,¹⁰ which is supported by an 8-year warranty¹¹
- 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 – complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP™) technology, the AF Suppression™ algorithm and SenseAbility™ technology – is designed to deliver optimal therapy for patients at implant and throughout their lives
- The only pacemaker with programmable AT/AF alerts specifically indicated for detecting atrial tachyarrhythmias, which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF¹²
- 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
PM2172	Endurity MRI™ Pacemaker	46 x 50 x 6	19	10,4 (± 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. **Dual-Chamber Pacing** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. **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. AF Suppression algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: **Dual-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. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. **Dual-Chamber Pacing**, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients.

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.

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™

Dual-Chamber Pacemaker

Product Specifications - Pacemaker

PHYSICAL SPECIFICATIONS	
Model	PM2172
Telemetry	Inductive
Dimensions (mm)	46 x 50 x 6
Weight (g)	19
Volume (cc)	10.4 ¹
Connector	IS-1
Remote Monitoring	
Compatible with Merlin@home™ Transmitter	
PARAMETER	SETTINGS
Rate/Timing	
Atrial Pace Refractory (ms)	190-400 in steps of 30; 440; 470 ²
Atrial Sense Refractory (ms)	93; 125; 157; 190-400 in steps of 30; 440; 470 ²
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min ⁻¹)	30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16 ³
Hysteresis Rate (min ⁻¹)	Off; 30 ⁴ -150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min ⁻¹)	Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30
Intervention Duration (min)	1-10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Maximum Tracking Rate (min ⁻¹)	90-130 in steps of 5; 140-210 in steps of 10
Mode	A00(R); AAI(R); AAT(R); V00(R); VVI(R); VVT(R); VDD(R); D00(R); DVI(R); DDI(R); DDD(R); Pacing Off
Post Ventricular Atrial Blanking (ms)	60-200 in steps of 10; 225; 250
PVARP (ms)	125-500 in steps of 25
Sensed AV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min ⁻¹)	Off; 30-150 in steps of 5
Rate Responsive AV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest AV Delay (ms)	25-50 in steps of 5; 60-120 in steps of 10
Shortest PVARP/VREF (ms)	125-475 in steps of 25
Ventricular Blanking (ms)	Auto, 12-52 in steps of 4
Ventricular Pace/Sense Refractory ⁵ (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470; 500 ²
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5.0
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)
Ventricular AutoCapture™	
Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5.0 ⁶
Search Interval (hours)	8; 24
AutoCapture	
Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100
Atrial Sensitivity (mV)	0.1-0.4 ⁶ 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 ⁷
Ventricular Sensitivity (mV)	0.5-5.0 in steps of 0.5; 6-10 in steps of 1.0; 12.5 ⁷
SenseAbility™ Technology	Off; On (Automatic Sensitivity Control adjustment for atrial and 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 (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
Decay Delay (ms)	
Rate-Modulated Parameters	
Maximum Sensor Rate (min ⁻¹)	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 Slope	On; Off; Passive
Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1	
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	
Threshold	
AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min ⁻¹)	10 ³
Upper Rate Overdrive (min ⁻¹)	5 ³
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12 ³
Maximum AF	

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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Suppression Rate (min ⁻¹)	80-200 in steps of 10; 225-300 in steps of 25		
Atrial Tachycardia			
Detection Rate (min ⁻¹)	110-200 in steps of 10; 225-300 in steps of 25		
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)		
AMS Base Rate (min ⁻¹)	40-170 in steps of 5		
Stored Electrograms			
Options			
Priority Options	Off; Low; High		
Channel	1; 2; 3		
Triggers			
Advanced Hysteresis	Off; Low; High		
AMS Entry/AMS Exit/			
AMS Entry and Exit	Off; Low; High		
AI/AF Detection	Off; Low; High		
Magnet Response	Off; Low; High		
High Atrial Rate	Off; Low; High		
Rate (min ⁻¹)	125-300 in steps of 25		
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20		
High Ventricular Rate	Off; Low; High		
Rate (min ⁻¹)	125-300 in steps of 25		
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20		
PMT Termination	Off; Low; High		
Consecutive PVCs	Off; Low; High		
No. of Consecutive PVCs	2; 3; 4; 5		
Noise Reversion	Off; Low; High		
Other			
A and V Lead Monitoring	Monitor; Auto Polarity Switch		
A and V Low Impedance Limit (Ω)	100-500 in steps of 25		
A and V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000		
Lead Type	Uncoded; Unipolar; Bipolar		
Magnet Response	Off; Battery Test		
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10		
NIPS Options			
Stimulation Chamber	Atrial; Ventricular		
Coupling Interval (ms)	100-800 in steps of 10 ⁸		
SI Count	2-25 in steps of 1		
SP ¹ ; S2, S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)		
Ventricular Support Rate (min ⁻¹)	Off; 30-95 in steps of 5		
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5		
PMT Options	Off; Passive; Atrial Pace ²		
PVC Detection Rate (min ⁻¹)	90-180 in steps of 5		
PVC Response	Off; Atrial Pace ²		
Ventricular Intrinsic			
Preference, VIP™ (ms)	Off, 50-150 in steps of 25; 160-200 in steps of 10		
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.		
VIP Search Cycles	1; 2; 3		
Ventricular Safety Standby	Off; On		
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold		
MRI Settings			
MRI Mode	A00; V00; D00; Pacing Off		
MRI Base Rate	30-120 bpm in steps of 5 bpm		
MRI Paced AV Delay	25 ms; 30-120 ms in steps of 10 ms		
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		
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	
IsoFlex1948 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

- ± 0.5 cc
- Programming options dependent on pacing mode.
- This parameter is not programmable.
- The highest available setting for hysteresis rate will be 5 min⁻¹ below the programmed base rate.
- In dual-chamber modes, the maximum ventricular refractory period is 325 ms.
- Values 0.1-0.4 not available in a unipolar sense configuration.
- Sensitivity is with respect to a 20 ms haversine test signal.
- During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.
- SI Burst Cycle is applied at the preprogrammed SI cycle length.
- A.V = 2.5 V @ 0.4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGms ON
- Terms and conditions apply; refer to the warranty for details.
- Healey JS, Connolly SJ, Gold MR, et al. on behalf of the ASSERT investigators. Sub-clinical atrial fibrillation and the risk of stroke: A symptomatic atrial fibrillation and Stroke Evaluation in pacemaker patients and the AF Reduction atrial pacing Trial (ASSERT). N Engl J Med 2012; 366:120-129.

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 ²
Ring Electrode (Anode)	Titanium-nitride-coated Pt/Ir
Ring Electrode Surface Area	16 mm ²
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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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. 00

Manufacturer:

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

EC-Representative:

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

Product:

Implantable Pacemakers

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.:

713149860

Valid from:

2019-06-15

Valid until:

2024-05-26

Date,

2019-06-14

Stefan Preiß



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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. 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

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



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Product Service

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

No. I7 014607 0234 Rev. 00

Test Report No.: 71321436

Model:

Zephyr™ XL SR

Model No.:

5626

Variant:

Test Report No.: 713017309_1

Model:

Assurity™

Assurity™

Endurity™

Endurity™

Allure™

Allure™ RF

Allure Quadra™ RF

Model No.:

PM1240

PM2240

PM1160

PM2160

PM3120

PM3222

PM3242

Variant:

Test Report No.: 713028360

Model:

Quadra Allure MP™RF

Model No.:

PM3262

Variant

Test Report No.: 713043621

Model:

Assurity MRI™

Assurity MRI™

Endurity MRI™

Endurity MRI™

Endurity™

Endurity™

Model No.:

PM1272

PM2272

PM1172

PM2172

PM1162

PM2162

Variant:

MR Conditional

MR Conditional

MR Conditional

MR Conditional

MR Conditional

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. 00

Test Report No.: 713057320

Model:

Endurity™ Core
Endurity™ Core
Endurity™ Core
Endurity™ Core

Model No.:

PM1140
PM2140
PM1152
PM2152

Variant:

MR Conditional
MR Conditional
MR Conditional
MR Conditional

Test Report No.: 713084189

Model:

Quadra Allure™
Quadra Allure MP™

Model No.:

PM3542
PM3562

Variant:

MR Conditional
MR Conditional

Test Report No.: 713130819

Model:

Zenex™
Zenex™
Zenex™
Zenex™
Zenex MRI™
Zenex MRI™
Zenex MRI™
Zenex MRI™

Model No.:

PM1250
PM2250
PM1170
PM2170
PM1282
PM2282
PM1182
PM2182

Variant:

MR Conditional
MR Conditional
MR Conditional
MR Conditional



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. 00
Expiration Date: 2024-05-26*

*FQA
Certificate No: I1 16 12 14607 211
Expiration Date: 2021-07-25*

*ISO13485
Certificate No: Q1N 17 09 14607 217
Expiration Date: 2020-10-31*

Signature:

Kathy Berg
Kathy Berg
Manager Regulatory Affairs

14 Jun 2019
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

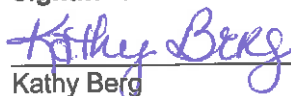
Manufacturing Facilities:

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
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 0230 Rev. 00:**

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

Kathy Berg
Manager Regulatory Affairs

14 Jun 2019

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

Signature:



Kathy Berg
Manager Regulatory Affairs



Issue Date



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

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

A handwritten signature in blue ink, appearing to read 'Markus Bleher'.

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Bratului nr. 11, 020565 Bucharest - Romania



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.