Fortify Assura™ VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)

Implantable Cardioverter Defibrillator (ICD) Devices

Merlin@home™ Transmitter Compatible

MR

Product Highlights

- MRI ready device has been tested for safe performance of an MRI scan using a 1,5 T (Tesla) field-strength MRI scanner when used in combination with an MRI conditional lead[1,2]
- Parylene coating for improved abrasion resistance
- DynamicTx™ Over-current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold Can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD™ morphology discrimination and Chamber Onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Low Frequency Attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ sensing algorithm feature provides flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- CorVue™ congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST-segment as a diagnostic tool to help guide appropriate clinical action
- Unique 40 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR™† chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries

Ordering Information

Contents: Implantable Cardioverter Defibrillator (ICD)

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD1359-40C	73 x 40 x 14	76	35	DF1	IS-1
CD1359-40QC*	71 x 40 x 14	75	35	DF4	DF4

*Indicates models that are MRI Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications: Contraindications for use of the implantable cardioverter defibrillator (ICD) include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the ICD, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

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

†QHR is a trademark of Greatbatch Medical

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Product Specifications

Physical Specifications

Models	CD1359-40C	CD1359-40QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	73 x 40 x 14	71 x 40 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene
MRI Conditional	No	Yes - MRI ready

Parameter	Settings
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2-3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone, 2 zones or 3 zones (VT-1; VT-2; VF)
SVT Discriminators	Sudden Onset; Interval Stability; Sinus Interval History; Morphology Discrimination (Far Field MD™ or Original MD) with Manual (Original MD) or Automatic Template Update
Discrimination modes	On; Passive; Off
SVT Threshold	150-240 min^{-1}
SVT Timeout	0,25-5 min
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination (On; On with Timeout; Passive; Off)
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150 - 300 min^{-1}
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 5
Number of Bursts	1-15
Number of Stimuli	2-20
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DynamicTx™ Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; VVI(R)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	(Post-Sense/Post-Pace; Ventricular) 0-220
Programmable	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Sensor Rate (min^{-1});
Rate Parameters	Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
Post-Shock Base Rate (min^{-1})	30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 7,5; or 10
Device Testing/Induction Methods	
DC Fibber™ Pulse Duration (sec)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to 3 extrastimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; %V pacing; CorVue™ Congestion Trigger; SecureSense lead noise detected, non-sustained lead noise detected, ST Episodes (Type I only)
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 45 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; detection; therapy; PC shock delivery; noise reversion; magnet reversion; and morphology template verification; lead noise detected, non-sustained lead noise detected, NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; ; DirectTrend™ viewer reports up to 1 year
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode, VT/VF, Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

MRI Scan Restrictions

Lead Model	Whole Body SAR	Scan Zone Restrictions
Durata™ Lead		**If MRI Mode is "Pacing Off":** **Superior:** Isocenter at or above the eye level **Inferior:** Isocenter at or below the L2 vertebra **If MRI Mode is "VOO" or "DOO":** **Superior:** Isocenter 10 cm above the eye level **Inferior:** Isocenter at or below the L4 vertebra
7120Q (lead lengths: 58 cm, 65 cm)	≤ 2 W/kg	
7122Q (lead length: 58 cm)	≤ 2 W/kg	
7122Q (lead length: 65 cm)	≤ 1.6 W/kg	
Optisure™ Lead		
LDA220Q (lead lengths: 58 cm, 65 cm)	≤ 2 W/kg	
LDA210Q (lead length: 58 cm)	≤ 2 W/kg	
LDA210Q (lead length: 65 cm)	≤ 1.6 W/kg	

1. MRI Conditional Field Strength 1,5 Tesla
2. See MRI Procedure Information for approved MR-conditional Systems Device/Lead combinations and scan parameters

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.

SJM-FRT-0415-0005(1) | Item approved for international use only.

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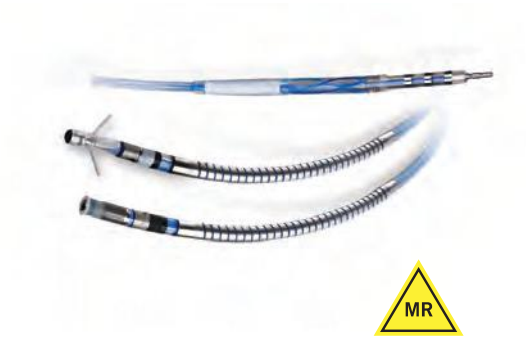
Durata™

Defibrillation Lead



Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an SJM MRI Ready device.[1,2]
- Optim™ insulation is a chemical co-polymer that offers superior handling and durability[3]
- Two innovative designs are intended to help prevent tissue ingrowth – flat-wire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space
- Redundant conductors serve as a backup system in the unlikely event of a conductor failure
- Symmetrically aligned cables within the lead body and centrally located coil provide for additional protection to the inner coil[4]
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws

Ordering Information

Contents: Defibrillation lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Shock Configuration	Sensing	Tip-to-Proximal Coil (cm)	Connector	Lengths (cm)
7120	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65
7120Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF4	52; 58;*65*
7121	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7121Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7122	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF1; IS-1	60; 65; 75
7122Q	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF4	52; 58;*65*
7170	Optim	Tines	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65; 75
7170Q	Optim	Tines	7	Dual-coil	True bipolar	17	DF4	52; 58; 65
7171	Optim	Tines	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7171Q	Optim	Tines	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7172Q	Optim	Tines	7	Single-coil	True bipolar	N/A	DF4	52; 58; 65

*Indicates models and lead lengths that are MRI Conditional[1,2]

Indications for Use: The Durata™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart. A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation. If the initial lead configuration is not effective, repositioning of the lead or other lead configurations should be attempted. In some patients, a nonthoracotomy lead configuration may not provide reliable conversion of arrhythmias, and the use of subcutaneous or epicardial patch defibrillation leads should be considered.

Contraindications: Contraindications for use of the Durata leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Durata leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. The Durata leads are contraindicated for extra firm (red color knob) stylets. The lead is not designed, sold, or intended for use other than as indicated.

1. St. Jude Medical DF1 lead connectors conform to the international connector standard ISO 11318/Amd.
2. St. Jude Medical IS-1 lead connectors conform to the international connector standard ISO 5841.
3. St. Jude Medical DF4 lead connectors conform to the international connector standard ISO 27186: 2010 (E).

Potential Complications: Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis and erosion of the skin. Specific events and effects are summarised below:

WARNING: Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture and anatomical influences Cardiac leads' functional lifetimes can be affected by these and other factors.

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

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Durata™

Defibrillation Lead

Product Specifications

PHYSICAL SPECIFICATIONS

True Bipolar, Active-Fixation Defibrillation Leads

Models	7120	7120Q	7121	7121Q	7122	7122Q
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65	52; 58; 65	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF1; IS-1	DF4
Body Diameter	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	N/A	N/A
Tip Electrode Area	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	N/A	N/A
MRI Conditional	No	Yes, MRI-ready (lengths: 58 and 65 cm)	No	No	No	Yes, MRI-ready (lengths: 58 and 65 cm)

True Bipolar, Passive-Fixation Defibrillation Leads

Models	7170	7170Q	7171	7171Q	7172Q
Fixation	Tines	Tines	Tines	Tines	Tines
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF4
Body Diameter	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	N/A
Tip Electrode Area	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	N/A
MRI Conditional	No	No	No	No	No

1. MRI Conditional Parameters: 1,5 Tesla, 2 W/Kg SAR
2. See MRI Procedure Information for approved MR Conditional Systems Device/Lead combinations and scan parameters
3. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance, Heart Rhythm, 2, S318-S319 (2005).
4. St. Jude Medical Engineering Report: Tension and Cable Shortening Comparison. Report 60032635

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.

SJM-DUR-1114-0001 I This document is for international use only.

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

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 17 07 14607 216

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 Cardioverter / Defibrillators**

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.: 713106728

Valid from: 2017-09-26
Valid until: 2022-09-25

040052767321948

Date, 2017-09-25

Stefan Preiß

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

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

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 17 07 14607 216

Model(s): see attachment

Parameters: ./.

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

St. Jude Medical Coordination Center BVBA
European Distribution Center, BruCargo 831, 1931 BruCargo,
BELGIUM

Design Facility(ies):

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

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

Product Service

Attachment for Certificate no I7 17 07 14607 216
dated 2017-09-25

Product: **Implantable Cardioverter / Defibrillators**

Test Report No.: 71362982

Model:	**Model No:**
Fortify™ VR	CD1233-40, CD1233-40Q
Fortify™ DR	CD2233-40, CD2233-40Q
Unify™	CD3235-40, CD3235-40Q

Test Report No.: 71376924

Unify Quadra™	CD3251-40, CD3251-40Q

Test Report No.: 713000600 / 713000540

Ellipse™ VR	CD1275-36, CD1275-36Q,
Ellipse™ DR	CD2275-36, CD2275-36Q,

Test Report No.: 713015987_1

Quadra Assura™	CD3367-40, CD3367-40C
Quadra Assura MP™	CD3371-40, CD3371-40C
Unify Assura™	CD3361-40, CD3361-40C CD3361-40Q, CD3361-40QC
Fortify Assura™ DR	CD2359-40, CD2359-40C
Fortify Assura™ VR	CD1359-40, CD1359-40C
Ellipse™ DR	CD2377-36, CD2377-36C
Ellipse™ VR	CD1377-36, CD1377-36C

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Product Service

Attachment for Certificate no I7 17 07 14607 216
dated 2017-09-25

Test Report No.: 713015987_1 / 713057341

Model:	**Model No:**	**Variants:**
Ellipse™ VR	CD1377-36Q, CD1377-36QC	MR Conditional
Ellipse™ DR	CD2377-36Q, CD2377-36QC	MR Conditional

Test Report No.: 713015987_1 / 713060615

Fortify Assura™ VR	CD1359-40Q, CD1359-40QC	MR Conditional
Fortify Assura™ DR	CD2359-40Q, CD2359-40QC	MR Conditional

Test Report No.: 713015987_1 / 713068024

Quadra Assura™	CD3367-40Q, CD3367-40QC	MR Conditional
Quadra Assura MP™	CD3371-40Q, CD3371-40QC	MR Conditional

Munich, MHS-CRT, 2017-09-25

Stefan Preiß
Certification Medical Technology

TÜV®

SJM Declaration of Conformity
Implantable Cardioverter/Defibrillators

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/Defibrillators
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 17 07 14607 216 Expiration Date: 2022-09-25 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
Manager Regulatory Affairs

07Nov2017
Issue Date

SJM Declaration of Conformity
Implantable Cardioverter/Defibrillators

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, Münich, 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
Manager Regulatory Affairs

07 Nov 2017
Issue Date

SJM Declaration of Conformity
Implantable Cardioverter/Defibrillators
ATTACHMENT TO DECLARATION OF CONFORMITY

The following product(s) is/are approved under EC-Certificate number **I7 17 07 14607 216.**

Product Name	Model No.	GMDN Code	First Date of CE Marking
Fortify™ VR	CD1233-40, CD1233-40Q	35852	2010-1-29
Fortify™ DR	CD2233-40, CD2233-40Q	37265	2010-1-29
Unify™	CD3235-40, CD3235-40Q	47270	2010-1-29
Unify Quadra™	CD3251-40, CD3251-40Q	47270	2011-3-15
Ellipse™ VR	CD1275-36, CD1275-36Q	35852	2012-2-3
Ellipse™ DR	CD2275-36, CD2275-36Q	37265	2012-2-3
Quadra Assura™ IS-1/DF-1	CD3367-40, CD3367-40C	47270	2012-12-18
Quadra Assura MP™ IS-1/DF-1	CD3371-40, CD3371-40C	47270	2012-12-18
Unify Assura™ IS-1/DF-1	CD3361-40, CD3361-40C CD3361-40Q, CD3361-40QC	47270	2012-12-18
Fortify Assura™ DR IS-1/DF-1	CD2359-40, CD2359-40C	37265	2012-12-18
Fortify Assura™ VR IS-1/DF-1	CD1359-40, CD1359-40C	35852	2012-12-18
Ellipse™ DR IS-1/DF-1	CD2377-36, CD2377-36C	37265	2012-12-18
Ellipse™ VR IS-1/DF-1	CD1377-36, CD1377-36C	35852	2012-12-18
Ellipse™ VR DF-4	CD1377-36Q, CD1377-36QC MR Conditional	35852	2015-05-11
Ellipse™ DR DF-4	CD2377-36Q, CD2377-36QC MR Conditional	37265	2015-05-11
Fortify Assura™ VR DF-4	CD1359-40Q, CD1359-40QC MR Conditional	35852	2015-7-14
Fortify Assura™ DR DF-4	CD2359-40Q, CD2359-40QC MR Conditional	37265	2015-7-14
Quadra Assura™ DF4	CD3367-40Q, CD3367-40QC MR Conditional	47270	2015-10-13
Quadra Assura MP™ DF-4	CD3371-40Q, CD3371-40QC MR Conditional	47270	2015-10-13

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