Fortify Assura™ VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)

Implantable Cardioverter Defibrillator (ICD) Devices

Product Highlights

Merlin@home™ Transmitter Compatible

MR

- 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

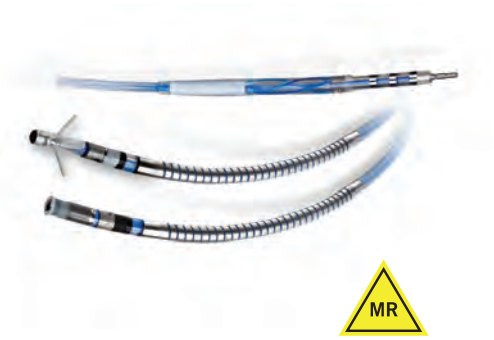
Customer Support: 46-8-474-4756

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.

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.

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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

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

No. G12 014607 0255 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 established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System 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:G12 014607 0255 Rev. 00

Report No.: 713262605

Valid from: 2022-08-15
Valid until: 2027-08-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-08-15

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Product Service

EU Quality Management System Certificate (MDR)

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

No. G12 014607 0255 Rev. 00

Classification:	III
Device Group:	J01900282 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS - SOFTWARE ACCESSORY
Intended Purpose:	-
Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-
Classification:	III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Intended Purpose:	-
Classification:	III
Device Group:	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 014607 0257 Rev. 00

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 0257 Rev. 00

Report No.: 713224396

Valid from: 2022-08-15
Valid until: 2027-08-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-08-15

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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 0257 Rev. 00

Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	5415067HVD0002GV
Intended Purpose:	The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, ICD devices can detect and treat • chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle • various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium
Device(s):	Fortify™ VR, Fortify Assura™ VR, Ellipse™ VR. For device variants/models and parameters please see model list no. 1 at the end of the certificate.

Classification:	III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Basic UDI-DI:	5415067HVD0002GV
Intended Purpose:	The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, ICD devices can detect and treat • chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle • various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
Device(s):	Fortify™ DR, Fortify Assura™ DR, Ellipse™ DR. For device variants/models and parameters please see model list no. 2 at the end of the certificate.

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EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 014607 0257 Rev. 00

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

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

List no. 1:
Ellipse™ VR / CD1377-36C
Ellipse™ VR / CD1377-36Q
Ellipse™ VR / CD1377-36QC
Fortify™ VR / CD1233-40
Fortify™ VR / CD1233-40Q
Fortify Assura™ VR / CD1359-40
Fortify Assura™ VR / CD1359-40C
Fortify Assura™ VR / CD1359-40Q
Fortify Assura™ VR / CD1359-40QC

List no. 2:
Ellipse™ DR / CD2377-36C
Ellipse™ DR / CD2377-36QC
Fortify™ DR / CD2233-40
Fortify™ DR / CD2233-40Q
Fortify Assura™ DR / CD2359-40
Fortify Assura™ DR / CD2359-40C
Fortify Assura™ DR / CD2359-40Q
Fortify Assura™ DR / CD2359-40QC

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EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 014607 0257 Rev. 00

List no. 3:
Unify™ / CD3235-40
Unify™ / CD3235-40Q
Unify Quadra™ / CD3251-40
Unify Quadra™ / CD3251-40Q
Unify Assura™ / CD3361-40
Unify Assura™ / CD3361-40C
Unify Assura™ / CD3361-40Q
Unify Assura™ / CD3361-40QC
Quadra Assura™ / CD3367-40C
Quadra Assura™ / CD3367-40QC
Quadra Assura MP™ / CD3371-40
Quadra Assura MP™ / CD3371-40C
Quadra Assura MP™ / CD3371-40Q
Quadra Assura MP™ / CD3371-40QC

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

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

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

Intended Purpose:	IMPLANTABLE SINGLE CHAMBER AND DUAL CHAMBER DEFIBRILLATORS The Implantable Cardioverter Defibrillator (ICD) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, ICD devices can detect and treat • chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle • various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, these devices can detect and treat chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium. CRT-D devices sense cardiac activity and provide pacing to resynchronize the right and left ventricles.
Risk Classification:	**Class III** as per EU MDR 2017/745 per Annex VIII
Classification Rationale:	Annex VIII, Rule 8, 6th Indent
EMDN Code(s):	See attached Product List
Basic UDI-DI:	See attached Product List

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

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

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

Notified Body:	TÜV SÜD Product Services GmbH Ridlerstraße 65 80339 Munich Germany ID Number: 0123
Supporting Certificate(s):	Quality Management System Certificate: G12 014607 0255 Rev. 00 Expiration Date: 2027-08-14 Technical Documentation Assessment Certificate: G70 014607 0257 Rev. 00 Expiration Date: 2027-08-14
Original CE Mark Date:	See attached Product List
Conformity Assessment:	EU MDR 2017/745, Annex IX
Device Photograph:	Not Applicable. Identification and traceability achieved through Model Numbers on the attached Product List.

The products in the attached Declaration of Conformity Product List are approved under EC Certificate G70 014607 0257 Rev. 00

Declaration of Conformity Product List

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

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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

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

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TÜV

CERTIFICATE

This is to certify that

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.

This annex (edition:2021-06-16) is only valid in connection with the above-mentioned certificate.