Quadra Assura™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

Product Highlights

- The Quadra Assura CRT-D and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to minimise implant complications such as diaphragmatic stimulation and high pacing thresholds
- VectSelect Quartet™ multivector testing feature offers a streamlined workflow to identify, test and program the patient's pacing vector
- DynamicTx™ Over-Current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Parylene coating for improved abrasion resistance
- 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
- 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
- Low Frequency Attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ 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
- 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
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- 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
- QuickOpt™ timing cycle optimisation provides quick and effective optimisation at the push of a button

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
CD3367-40C	83 x 41 x 14	83	40	DF1, IS4, IS-1
CD3367-40QC	75 x 41 x 14	80	38	DF4, IS4, IS-1

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the pulse generator system, 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 perforation/avulsion, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrinsic/ectopic 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

ST. JUDE MEDICAL

Quadra Assura™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD3367-40C**	**CD3367-40QC**
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	40	38
Weight (g)	83	80
Size (mm)	83 x 41 x 14	75 x 41 x 14
Defibrillation Lead Connections	DF1	DF4-LLHH
LV Lead Connections	IS4-LLLL	IS4-LLLL
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ LV	Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil; Pulse Configuration Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25-120
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Maximum AF Suppression Rate	80-150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2-3,0 mV; Threshold Start (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2-3,0 mV
Decay Delay	(Post-Sensed/Post-Paced; Atrial/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	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association; Morphology Discrimination (Far Field MD or Original MD) with Manual (original MD only) or Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination modes	On; Passive; Off
SVT Threshold	150-240 min^{-1}
SVT Timeout	0; 25-5 min
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/Stimuli	1-15 with 2-20 Stimuli
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; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	Setup; On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Interventricular Pace Delay
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
AMS Base Rate (min^{-1})	40; 45; ... 135
Auto PMT Detection/Termination	Atrial Pace; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; On (50-200)
Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 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; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; AT/AF Episode Duration; % V Pacing; CorVue™ Congestion Trigger, SecureSense — lead noise detected, non-sustained lead noise detected
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 1 minute programmable pre-trigger data per VT/VF diagnosis; detection; electrograms; triggers include diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; 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
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS , DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

* LV first with 10 ms interventricular delay

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.

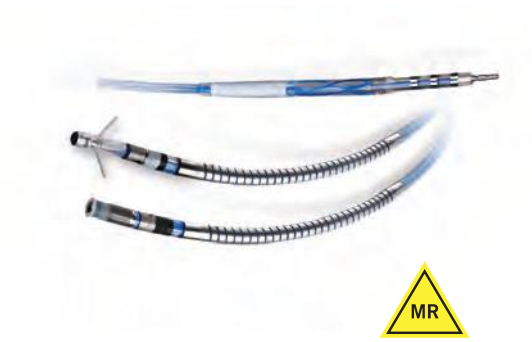
Item GMCRM1074EN

GMCRM1074EN

ST. JUDE MEDICAL™

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.

ST. JUDE MEDICAL

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.

ST. JUDE MEDICAL

1458Q

1456Q

1457Q

1458QL

Product Highlights

- Proven Quartet™ LV lead performance with the most Quadripolar lead options to match a patient's anatomy
- The Quartet™ Family of LV leads offers more distal shape options including the Large-S, Small-S and the Double Bend and more total electrode spacing options including 40, 47 and 60 mm
- Allows patients to safely undergo an MRI scan when used in combination with a St Jude Medical™ MRI Ready device[1,2]
- Four pacing electrodes to provide more options and greater control in pacing vector selection
- Superb deliverability with exceptional stability and performance
- Low profile—4,7 F lead body; 4,0 F lead tip
- Optim™ lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Steerable tip—distal tip angle can be controlled to maneuver through venous anatomy
- Flexible lead body—narrow ring electrodes provide lead tip flexibility
- Allows Direct-To-Target™ delivery placement through CPS Aim™ SL slittable inner catheter to deliver leads to small, acute venous anatomies that may have been unreachable in the past
- Compatible with over-the-wire or stylet approaches

Ordering Information

Contents: Left-heart lead

Model Number	Shape	Total Electrode Spacing (mm)	Insulation	Minimum Curve Height	Minimun Introducer (F)	Connector	Lengths (cm)
1458Q	Large-S	47	Optim™	16	5	IS4-LLLL	75; 86*; 92
1456Q	Small-S	40	Optim™	8	5	IS4-LLLL	75; 86*
1457Q	Double Bend	47	Optim™	16	5	IS4-LLLL	75; 86*
1458QL	Large-S	60	Optim™	16	5	IS4-LLLL	75; 86*

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

Indications and Usage: The Quartet lead has application as part of a St. Jude Medical biventricular system.
Contraindications: The use of the Quartet lead is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1,0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Physical Specifications

Models	1458Q	1456Q	1457Q	1458QL
Parameter	**Description**	**Description**	**Description**	**Description**
Connector	IS4-LLLL	IS4-LLLL	IS4-LLLL	IS4-LLLL
Lead Length	75; 86; 92 cm	75; 86 cm	75; 86 cm	75; 86 cm
Maximum Lead Size	5,1 F (1,70 mm/0,067") at the ring electrode	5,1 F (1,70 mm/0,067") at the ring electrode	5,1 F (1,70 mm/0,067") at the ring electrode	5,1 F (1,70 mm/0,067") at the ring electrode
Lead Body Size	4,7 F (1,57 mm/0,062")	4,7 F (1,57 mm/0,062")	4,7 F (1,57 mm/0,062")	4,7 F (1,57 mm/0,062")
Tip Electrode Size	4,0 F (1,3 mm/0,052")	4,0 F (1,3 mm/0,052")	4,0 F (1,3 mm/0,052")	4,0 F (1,3 mm/0,052")
LV Lead Delivery System Introducer Size	Minimum 5 F ID	Minimum 5 F ID	Minimum 5 F ID	Minimum 5 F ID
Minimum Curve Height	16 mm	8 mm	16 mm	16 mm
Tip Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves
Steroid	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate
Tip Electrode Surface Area	4,9 mm^2	4,9 mm^2	4,9 mm^2	4,9 mm^2
Ring Electrode Surface Area	7,4 mm^2	7,4 mm^2	7,4 mm^2	7,4 mm^2
Electrode Spacing				
Distal tip 1 - Mid 2	20 mm	20 mm	20 mm	20 mm
Distal tip 1 - Mid 3	30 mm	30 mm	30 mm	47 mm
Distal tip 1 - Proximal 4	47 mm	40 mm	47 mm	60 mm
Lead Body Insulation	Optim™ insulation	Optim™ insulation	Optim™ insulation	Optim™ insulation
Lead Body Coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating
Conductors				
Distal (coil)	MP35N™ LT†	MP35N™ LT†	MP35N™ LT†	MP35N™ LT†
Proximal (cables)	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT
Suture Sleeve	Attached	Attached	Attached	Attached
MRI Conditional	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)

†MP35N is a trademark of SPS Technologies, Inc.

1. MRI Conditional Parameters: 1,5 Tesla, 2 W/Kg SAR
2. See MRI Ready Systems Manual for approved MR Conditional Systems Device/Lead combinations and scan parameters

Customer Support: 46-8-474-4756

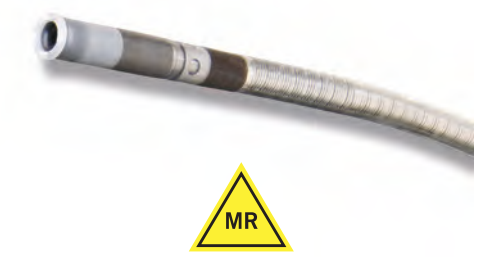
Rx Only
Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

SJM-QRT-1015-0011 I Item approved for international use only.

ST. JUDE MEDICAL

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.

ST. JUDE MEDICAL

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	DSO6002 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
	DSO6003 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.

SJM-TND-1214-0003 I This document is for International use only.

ST. JUDE MEDICAL™

CPS Direct™ Universal

Slittable Outer Guide Catheter

MODELS DS2C018, DS2C019, DS2C020, DS2C021, DS2C022, DS2C023, DS2C025, DS2C026, DS2C027, DS2C028, DS2C029

SPECIFICATIONS

- The CPS Direct Universal family of outer guide catheters is designed to facilitate left heart lead delivery. They are compatible with other products in the St. Jude Medical™ Cardiac Positioning System (CPS™) family – an inter-compatible system of tools designed to give you more control to efficiently and predictably deliver the left-heart lead to your vein of first choice.
- Enables Direct-To-Target™ delivery to the desired vein:
  - Soft, atraumatic tip with multi-durometer PEBAX™ shaft is designed to provide flexibility to allow advancement of the catheter deep into the coronary venous system.
  - CPS Direct™ Universal catheter is compatible with CPS Aim™ Universal inner catheters, designed to assist with branch vein subselection and left ventricular lead delivery , including delivery of the Quartet™ quadripolar LV lead.
- Designed to reduce procedural steps during implant:
  - Slittable hub and integrated shaft provide smooth transition during slitting of catheter.
  - U-channel valve bypass tool simplifies lead delivery.
  - Ergonomic slitter facilitates smooth slitting.
- Designed to provide reliable coronary sinus access:
  - Excellent torque transmission and soft, atraumatic tip due to braid-reinforced, multi-durometer PEBAX™* material design.
  - Unique SiteMark™ 3D markers provide fluoroscopic visibility to determine anterior/posterior location and verify torque transfer.
  - Six curve options to satisfy needs of various anatomies and different implanter techniques.
  - Compatible with CPS Aim™ Universal cannulators and CPS Luminary™ bideflectable catheter with lumen to modify shape and extend reach if necessary.
- Designed for worry-free removal:
  - Catheter design features Smooth-Slit™ braiding technology and ergonomic slitter, designed to allow effortless, best-in-class cutting, minimizing the risk of lead dislodgement upon catheter removal.

PEBAX is a trademark of Arkema Inc.

ST. JUDE MEDICAL™

PHYSICAL SPECIFICATIONS

Slittable Outer Guide Catheter

Models	CURVE SHAPE	AVAILABLE LENGTH	OVERALL LENGTH	INNER DIAMETER	OUTER DIAMETER
DS2C018	Straight	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C019	115°	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C020	135°	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C021	Wide	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C022	X-Wide	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C023	Right Side	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C025	Straight	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C026	115°	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C027	135°	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C028	Wide	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C029	X-Wide	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)

Material	Multi-durometer PEBAX™ material reinforced with stainless steel braid wire for a kink-resistant catheter shaft and soft distal tip. Lubricious coating on inner and outer surface.
Marker	Three gold marker bands and two tungsten stripes on distal tip.

ACCESSORIES

INCLUDED	SEPARATELY AVAILABLE
Dilator	CPS™ Universal Slitter
2 Valve bypass tools	CPS Direct™ Valve Bypass Tool
	Implant Kit

Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

St. Jude Medical Cardiovascular & Ablation Technologies
5050 Nathan Lane North
Plymouth, Minnesota 55442
USA
+1 651 756 5400
+1 651 756 5470 Fax

St. Jude Medical Implantable Electronic Systems
15900 Valley View Court
Sylmar, California 91342
USA
+1 818 362 6822
+1 818 364 5814 Fax

U.S. Division
6300 Bee Cave Road
Bldg. Two, Suite 100
Austin, TX 78746
USA
+1 512 286 4000
+1 512 732 2418 Fax

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Itapeva, 538
5º ao 8º andar
01332-000 – São Paulo – SP
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
+852 2996 7688
+852 2956 0622 Fax

St. Jude Medical Australia Pty, Ltd.
17 Orion Road
Lane Cove, NSW 2066
Australia
+61 2 9936 1200
+61 2 9936 1222 Fax

SJMprofessional.com

ST. JUDE MEDICAL™

CPS Aim™ Universal

Slittable Inner Catheter with Integrated Valve

MODELS DS2N026, DS2N027, DS2N028, DS2N029, DS2N030

SPECIFICATIONS

- The CPS Aim™ Universal family of inner catheters with integrated valve is designed to assist with coronary sinus cannulation, branch vein subselection and left ventricular lead delivery. The catheters are compatible with other products in the St. Jude Medical™ Cardiac Positioning System (CPS™) family–an inter-compatible system of tools designed to give you more control to deliver the left-heart lead–efficiently and predictably–to your vein of first choice.
- Three CPS Aim Universal inner catheters enable atraumatic subselection.
  - CPS Aim Universal inner catheters enable access to the vein of first choice through Direct-To-Target™ placement. The CPS Aim Universal inner catheter provides a tunnel to acute and tortuous venous anatomies for 5 F leads (including the Quartet™ lead) and guidewire.
  - The CPS Aim Universal inner catheters are easy to remove with a low slit force after Direct-To-Target™ placement.
  - Three curve shapes (acute, 90º, obtuse) with fluoroscopic visibility facilitate first-choice target vein access, even when encountering difficult angulations and tortuous anatomy.
  - The soft tip enables atraumatic subselection.
- Two CPS Aim™ cannulators assist with coronary sinus access
  - When used in conjunction with CPS Direct™ Universal outer guide catheters, CPS Aim™ Universal cannulators facilitate coronary sinus cannulation.
  - CPS Aim Universal cannulators help extend the reach and modify the shape of CPS Direct Universal outer guide catheters, helping overcome challenging anatomies.
- A combination of PEBAX™ material that becomes softer from the proximal to the distal end and increased braid wire at the distal end provide for a torqueable, kink resistant and soft-tipped subselector. The catheter has been designed to access acute and tortuous anatomies.
- The catheter body and tip are clearly seen under fluoroscopy. Fluoroscopic material in the catheter profile illuminates the catheter body. A platinum band at the tip provides a landmark to access venous anatomy.
- The CPS Aim Universal inner catheter has a low slit force to reduce the risk of lead movement when slitting the catheter. To assist in this effort, the CPS Aim Universal inner catheter has a slittable hub with a smooth hub-to-shaft transition. In addition, the braidwire and PEBAX material construction has been optimized for smooth slitting. The CPS Aim Universal slittable inner catheter has been designed to remove easily after Direct-To-Target™ placement.

ST. JUDE MEDICAL™

PHYSICAL SPECIFICATIONS

Model	DS2N026	DS2N027	DS2N028	DS2N029	DS2N030
Model Name	SUB-ACU	SUB-90	SUB-OBT	CN-CSL	CN-ALII
Curve Shape	Acute	90°	Obtuse	CSL	ALII
Available Lengths - cm (working)	59, 65	59, 65	59, 65	65	65
Overall Length - cm (respectively)	63, 69	63, 69	63, 69	69	69
Valve	Integrated				
Inner Diameter	5.87 F (1.96 mm)				
Outer Diameter	7.62 F (2.6 mm)				
Material	Multi-durometer PEBAX™ material reinforced with stainless steel braid wire for a kink-resistant catheter shaft and soft distal tip. Lubricious inner liner/outer coating.				
Marker	Platinum tip				

Accessories (available separately)

Accessory Name	CPS™ Universal Slitter (DS2A003)	CPS Direct™ Valve Bypass Tool (DS2A004)
Accessory Type	Slitter	Valve Bypass Tool

*PEBAX is a trademark of Arkema, Inc.

Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

St. Jude Medical Cardiovascular & Ablation Technologies
5050 Nathan Lane North
Plymouth, Minnesota 55442
USA
+1 651 756 5400
+1 651 756 5470 Fax

St. Jude Medical Implantable Electronic Systems
15900 Valley View Court
Sylmar, California 91342
USA
+1 818 362 6822
+1 818 364 5814 Fax

U.S. Division
6300 Bee Cave Road
Bldg. Two, Suite 100
Austin, TX 78746
USA
+1 512 286 4000
+1 512 732 2418 Fax

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Itapeva, 538
5º ao 8º andar
01332-000 – São Paulo – SP
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
+852 2996 7688
+852 2956 0622 Fax

St. Jude Medical Australia Pty, Ltd.
17 Orion Road
Lane Cove, NSW 2066
Australia
+61 2 9936 1200
+61 2 9936 1222 Fax

SJMprofessional.com

ST. JUDE MEDICAL™

Rx Only
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.

Thermodilution Catheter

Pulmonary Artery Monitoring Catheter and Biotray

Product	Material	Catheter Size	Lumen	Length	Balloon Volume(cc)	Thermistor Resistance (ohms)	Recommended Introducer Size	Radiopacity
THERMODILUTION CATHETER								
TD1504N	PVC	5F	4	90 cm	0.75	14K	6F	Sufficiently opaque to appear visible under conventional flouroscope illumination while in vivo
TD2504N	PU	5F	4	90 cm	0.75	14K	6F	
TD1604N	PVC	6F	4	110 cm	1.00	14K	7F	
TD2604N	PU	6F	4	110 cm	1.00	14K	7F	
TD1704N	PVC	7F	4	110 cm	1.50	14K	8F	
TD2704N	PU	7F	4	110 cm	1.50	14K	8F	
TD1755N	PVC	7.5F	5	110 cm	1.50	14K	8.5F	
TD2755N	PU	7.5F	5	110 cm	1.50	14K	8.5F	
PA MONITORING CATHETER								
TD1502N	PVC	5 Fr	2	90 cm	0.75	N/A	6F	
TD2502N	PU	5 Fr	2	90 cm	0.75	N/A	6F	
TD1602N	PVC	6 Fr	2	110 cm	1.00	N/A	7F	
TD2602N	PU	6 Fr	2	110 cm	1.00	N/A	7F	
TD1702N	PVC	7 Fr	2	110 cm	1.50	N/A	8F	
TD2702N	PU	7 Fr	2	110 cm	1.50	N/A	8F	
TD1603N	PVC	6 Fr	3	110 cm	1.00	N/A	7F	
TD2603N	PU	6 Fr	3	110 cm	1.00	N/A	7F	
TD1703N	PVC	7 Fr	3	110 cm	1.50	N/A	8F	
TD2703N	PU	7 Fr	3	110 cm	1.50	N/A	8F	

SPECIAL FEATURES

Optional Features	Suffix	Description
SAFETYWEDGE™	D	Catheter with SAFETYWEDGE™
Contamination Sleeve	X	Catheter without contamination sleeve
Non-coated tubing	N	Catheter with no coating on tubing
Stiff Body Tubing	F	Catheter with stiffer tubing

SAFETYWEDGE™ covered by U.S. Patent No. 5,007,919

1. Thomas Santora, MD; William Ganz, MD; Julian Gold, MD; Mark Wittman, MD; Beverley Leyerle, RN; H.J.C. Swan, MD, PhD; M. Michael Shabot, MD, "New method for monitoring pulmonary artery catheter location, "Critical Care Medicine". Vol. 19, No. 3, p. 422, 1991.
2. Jean-Francois Hardy, MD; Martin Morissette, MD; Jean Taillefer, MD; Rene Vauclair, MD; "Pathophysiology if Repture of the Pulmonary Artery by Pulmonary Artery Balloon-Tipped Catheters, "Anesthesia & Analgesia". Vol. 62, p. 925, 1983.

BIOPTIMAL INTERNATIONAL PTE. LTD.
36 Jalan Tukang
Singapore 619266
Tel: +65 6213 5777
Fax: +65 6213 5737
Email: sales@bioptimalg.com

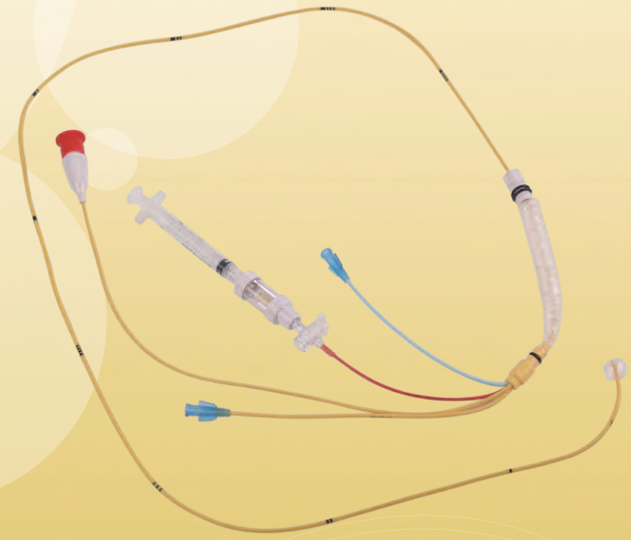
Bioptimal™

www.bioptimalg.com

Eliminating the risk of Pulmonary Artery Rupture.

Thermodilution Catheter

Pulmonary Artery Monitoring Catheter and Biotray



Bioptimal™

Thermodilution Catheter
Pulmonary Artery Monitoring Catheter and Biotray

Eliminating the risk
of Pulmonary Artery Rupture.

About SAFETYWEDGE™ Thermodilution Catheter
An unprecedented level of safety for balloon inflation.

Catheter tips often migrate to small arterial branches that are unable to safely accommodate inflated balloons.

SAFETYWEDGE™ thermodilution catheters virtually eliminate the risk of pulmonary artery rupture due to balloon overpressurization - the most serious complication associated with PA catheter monitoring.

SAFETYWEDGE™ catheters reduce the risk of this potentially dangerous situation by facilitating inflation of the SAFETYWEDGE™ device when either (1) the distal balloon encounters abnormal resistance to inflation, or (2) the pressure inside the distal balloon exceeds the normal inflation pressure.

SAFETYWEDGE™ component acts as a pressure relief valve to prevent overpressurization of the distal balloon.

This not only averts vessel rupture but balloon rupture as well, and alerts the clinician to reposition the catheter.

Features and Benefits

- **SAFETYWEDGE™**
  Exclusive Safety balloon acts as pressure relief valve to prevent overpressurization of the balloon.
- **Contamination Shield**
  Provides a protective barrier against contamination of the catheter during catheter insertion and manipulation.
- **Medication Lumen**
  Permits blood sampling, fluid and drug administration and central venous pressure monitoting *(7.5 French catheter only)*.
- **Thermistor Connector**
  Compatible with commonly used cardiac output computers, also used to monitor pulmonary artery blood temperature.
- **PA Distal Lumen**
  Allows mixed venous blood sampling, and measurements of pulmonary artery and pulmonary capillary wedge pressure.
- **Distal Balloon**
  Provides excellent symmetry and tip coverage for the safe flotation of the catheter and for pulmonary capillary wedge pressure measurements.
- **CVP Proximal or Injectate Lumen**
  Carries cardiac output injectate solution to right atrium. Accommodates blood sampling, fluid and drug administration and - when attached to a pressure transducer -monitor of right atrium pressure.

Correct catheter position, with SAFETYWEDGE™ device in READY mode.

Catheter tip migration into small PA branch, SAFETYWEDGE™ device activated upon attempt to inflate distal balloon.

SAFETYWEDGE™ Thermodilution Catheter with the Biotray
Reducing the Serious Risk of Pulmonary Artery Rupture.

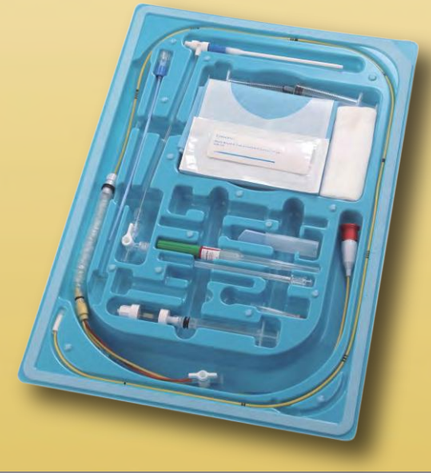
The BioTray contains all the necessary supplies used with the SAFETYWEDGE™ thermodilution catheter.
Value added benefits:

- Elimination of the sheath-catheter size compatible issue
- Ease of use
- Convenience
- Easier inventory control
- Elimination of nursing cover as the tray can be opened in a sterile area
- All components matched by BIOPTIMAL for optimum compatibility

Contents of the Biotray

Features high quality products at lower costs, saves time and reduces supply inventories.

- One Thermodilution Catheter / PA Monitoring Catheter
- Contamination Shield
- SAFETYWEDGE™ Balloon Device
- Venous Introducer with Dilator
- Guidewire (0.035")
- Needle 18G x 2 1/2"
- Needle 18G x 2 1/2" OTN Catheter
- Paper Towel 17 x 22"
- Gauze Swab
- Syringe Luer Slip 5cc
- Scalpel #11 Short
- Needle 25G
- Needle 22G
- Drape Minor Proc. Fen 22 x 22"
- Syringe
- Suture, Silk

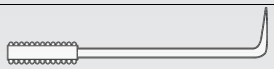
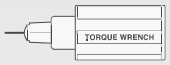
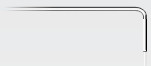
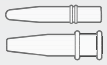
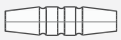
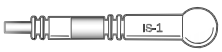


Advantage of PU catheter

- Polyurethane performs better against thrombosis, eliminating the need for Heparin coating.
- Polyurethane is tough, biocompatible, and hemocompatible. Polyurethane also outperforms many other materials in flexibility, tear resistance and abrasion resistance.
  Polyurethane is stiff when insert the catheter however after it goes into vein and contacts blood it will become soft which can reduce the risk of damage and injury to the vein wall.
- The use of Polyurethane in Bioptimal's thermodilution catheters eliminates the problems associated with other materials such as PVC, where the dangers of leachable plasticizers has become a concern.
- Polyurethane is radiopaque material which can be detected clearly to ensure correct placement of the catheter.

Total Package, Total Solution
Enjoy the benefits of the **SAFETYWEDGE™** thermodilution catheter in a convenient, fully accessorised all-in one tray.

Bioptimal™

Model Number	Receptacle (for adapting from)
AC-0160	Test Magnet 90 gauss at 1"
60007717-001	Vein Pick 
442-2	Torque Wrench (#2) 
437-246	Set of “L” Hex Wrenches (#2, #4, #6) 
4033A	DF4/IS-1/DF-1 Lead Terminal Cap 
6201	FasTac™ Flex Epicardial Lead Implant Tool
4080	Lead Removal Tool
DS0A001	Suture Sleeve (radiopaque 7.0 F) 
AC-0130	Silicone Oil
424	Medical Adhesive
FL-1056	Lead Flushing Tool
4071	Torque Tool and Tip Introducer
AC-IP-2	IS-1 Port Plug
AC-DP-3	DF-1 Port Plug 
AC-IS4PP	IS4/DF4 Port Plug
4078G	Custom Floppy Firm Guidewire, Straight, 5 cm Floppy Tip, 180 cm, 0.014", PTFE Coated
EX3151	IS4/DF4 Connector Sleeve

FasTac is a trademark of Greatbatch Medical.

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-CAG-0915-0036 I Item approved for international use only.

ST. JUDE MEDICAL

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

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

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

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

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

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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

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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

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Barbatului 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.

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