

SJM Confirm™

Implantable Cardiac Monitor
Model DM2102



FEATURES

Accurately Detect Atrial Fibrillation (AF) and Rhythm Disturbances with the SJM Confirm Implantable Cardiac Monitor (ICM)

The SJM Confirm ICM DM2102 is an implantable patient-activated and automatically activated monitoring system that records subcutaneous ECGs and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- Patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing AF

Customize and Prioritize Data Storage Options

The SJM Confirm ICM DM2102 offers simple-to-configure data storage options to enable physicians to prioritize data based on individual patient conditions, ensuring capture of significant events and to reduce the risk that unexpected events are missed. Options include:

- Programmable AF Episode Duration- >30 sec, >1 min, >2 min, >5 min, >10 min
- Programmable pre- and post-trigger event storage (auto activation: pre-event storage 10-60 sec; post-event storage 10-60 sec; patient-triggered activation: pre-event storage 60-240 sec; post-event storage 30-60 sec)
- Manual (patient-triggered) and automatic activation for EGM storage
- Additional programmable options (asystole [duration]; bradycardia [rate]; tachycardia [rate, cycle count])
- 48 minutes of stored electrograms

Receive Vital Information through Extensive Data Reports

Comprehensive diagnostic data reports provide a quick and accurate summary of heart rate, assisting physicians in their diagnosis and treatment of the patient's condition. Reports include:

- AF burden up to 18 months
- Episodic diagnostics for auto-trigger events
- Episode duration
- Episode count
- Episode date/time stamp
- Heart rate histogram

Improve Signal Detection with the Proven SenseAbility® Feature

The proven St. Jude Medical SenseAbility® feature is designed to allow accurate sensing over a wide range of signals, specifically offering more sensitive QRS detection. The feature also includes detection inhibitors for noise response and activity response.

Reduce Risk with the Smallest ICM Available

The small 6.5 cc size of the SJM Confirm ICM DM2102 is designed to reduce the risk of infection during the implant procedure by requiring a smaller incision and a smaller subcutaneous pocket. A small device footprint may also reduce implant time and means less change in body image for patients.

Simplify the Implantation Procedure with Subcutaneous Electrodes

The SJM Confirm ICM is intended to be placed using a minimally invasive approach. Subcutaneous electrodes simplify the implant procedure by eliminating the need for a transvenous lead system. Located on opposite sides of the device, the electrodes are designed to provide better episode detection due to consistent contact at the sensor-tissue interface.

Expand Evaluation Periods with Extended Longevity

The SJM Confirm ICM is designed to provide up to three years of reliable device monitoring.

Streamline Follow-Up with the Merlin™ Patient Care System

The SJM Confirm ICM is compatible with the St. Jude Medical Merlin Patient Care System (PCS). This allows physicians to quickly and easily access patient data and view real-time ECGs.

Facilitate Data Retrieval with Remote Monitoring

The system offers transtelephonic monitoring (TTM) capability, enabling timely and accurate data to be transmitted directly from the patient to the physician and streamlining evaluation of the patient's condition.

MR Conditional

The SJM Confirm ICM can be scanned in patients under the following conditions:

- Closed bore, cylindrical magnet
- Static magnetic field strength of 1.5 Tesla (T) only
- Maximum gradient slew rate 200 T/m/s per axis
- Whole body Specific Absorption Rate (SAR) less than or equal to 4.0 W/kg
- The uninterrupted duration of active scanning (when radio frequency (RF) and gradients are on) over the chest during MRI must not exceed 60 minutes
- Confirmation of absence of other contraindicated implantable devices and/or leads, including abandoned leads, lead extenders and lead adaptors

In non-clinical testing, the St. Jude Medical MR Conditional SJM Confirm ICM produced a temperature rise of less than 3°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3.9 W/kg as displayed on the MR scanner console for 60 minutes of MR scanning in a 1.5T closed bore MR scanner (manufacturer Philips, model Intera 1.5, Software version: 9.5.2).

SJM Confirm Implantable Cardiac Monitor

MODEL DM2102

SPECIFICATIONS

PARAMETERS	Description
Sampling Rate (Hz)	128
Dimensions (mm)	56.3 x 18.5 x 8
Volume (cc)	6.5
Weight (g)	12
Electrode Spacing (mm)	39
Electrode Minimum Surface Area (mm ²)	30

FEATURES

Longevity	3 years
Patient Trigger	Yes
Auto Activation Trigger	Yes
Atrial Fibrillation Trigger	Yes
Programmable AF episode duration	>30 sec, >1 min, >2 min, >5 min, >10 min
Tachycardia Trigger	Yes
Tachycardia Cycle Count	Yes
Bradycardia Trigger	Yes
Asystole (duration) Trigger	Yes
EGM Storage	48 minutes
Patient Trigger	Yes, Programmable ■ Pre-Trigger, 60-240 sec ■ Post-Trigger, 30-60 sec
Auto Activation	Yes, Programmable ■ Pre-Trigger, 10-60 sec ■ Post-Trigger, 10-60 sec
Activity Response	Inhibit, Monitor, Off
Noise Response	Inhibit

DIAGNOSTICS

Episodal Diagnostics	Yes
Heart Rate Histogram	Yes
Mean Heart Rate	Yes
Remote Monitoring	Transtelephonic monitoring (TTM)*
Patient Activator (PA)	Battery-powered PA (Model DM2100A)
Programming Device	Merlin Patient Care System

*Connectivity depends upon country and use of a compatible receiver unit. Please contact your St. Jude Medical sales representative for more details.

ATRIAL FIBRILLATION

CARDIAC RHYTHM MANAGEMENT

CARDIOVASCULAR

NEUROMODULATION

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

Atrial Fibrillation Division
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

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

SJMprofessional.com



Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Not available for sale in the United States. Products referenced within are CE marked.

SJM Confirm, Merlin, ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2012 St. Jude Medical. All Rights Reserved.

Item 100053753 Rev B



SJM Declaration of Conformity Impl. Monitoring and Recording Systems

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

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

European Representative: *St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium*

Product Type: *Impl. Monitoring and Recording Systems*

Product Name(s): *See attachment*

Model Number(s): *See attachment*

Classification: *AIMD*

GMDN Code(s): *See attachment*

Original CE Mark Date: *See attachment*

Certificate No. and expiration date: *EC Certification No: I7 014607 0141 Rev. 02
Expiration Date: 2023-09-24*

*FQA
Certificate No: I1 014607 0211 Rev. 01
Expiration Date: 2024-05-26*

*EN ISO 13485:2016
Certificate No: Q5 014607 0231 Rev. 00
Expiration Date: 2022-03-31*

Signature:

Kathy Berg

Kathy Berg
Sr. Manager Regulatory Affairs

22 APR 2020

Issue Date

SJM Declaration of Conformity Impl. Monitoring and Recording Systems

Applicable Quality System Standards:

Fulfills the requirements of Annex 2 of the European Union's Active Medical Devices Directive, AIMDD, 90/385/EEC/corresponding national legislation

Fulfills applicable requirements including CE marking and the Essential Requirements of AIMDD, 90/385/EEC/corresponding national legislation

Notified Body:

TÜV SÜD Product Service GmbH Zertifizierstelle
Ridlerstraße 65, 80339, München, Germany

Notified Body Number:

0123

Manufacturing Facilities:

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

Signature:



Kathy Berg
Sr. Manager Regulatory Affairs



Issue Date



**SJM Declaration of Conformity
Impl. Monitoring and Recording Systems
ATTACHMENT TO DECLARATION OF CONFORMITY**

The following product(s) is/are approved under EC-certificate number I7 014607 0141 Rev. 02:

Product Name	Model Number	Variant	GMDN Code	Date of First CE Marking
SJM CONFIRM™ Implantable Cardiac Monitor	DM2102	MR Conditional	47804	2008-09-25
SJM CONFIRM™ External Patient Activator	DM2100A	N/A	47805	2008-09-25

Signature:

Kathy Berg
Sr. Manager Regulatory Affairs

Issue Date



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](http://www.tuvsud.com/ps-cert?q=cert:Q5_014607_0231_Rev._03)

Report No.: 713237689

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

Date, 2022-08-12

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 014607 0231 Rev. 03

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

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

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

Abbott Medical
645 Almanor Avenue, Sunnyvale CA 94085, USA

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

CERTIFICATE



This is to certify that



SANTE
INTERNATIONAL S.A.

SANTE INTERNATIONAL S.A.

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

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

Scope:

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

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

ISO 9001 : 2015

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



DQS GmbH

Markus Bleher
Managing Director

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