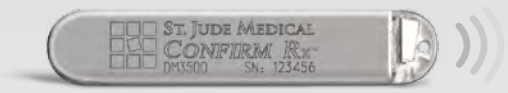
Confirm Rx™

Model DM3500

Insertable Cardiac Monitor

Insertable Cardiac Monitor



The St. Jude Medical™ Confirm Rx™ insertable cardiac monitor is designed to detect arrhythmias and wirelessly transmit data to the Merlin.net™ Patient Care Network for the following patients:

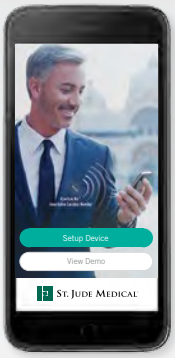
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who have been previously diagnosed with AF or who are susceptible to developing AF

Product Highlights

Device

- Small size (~1.4 cc) with slim profile
- Simple insertion procedure requiring minimal time and resources
- Intuitive one-touch programming on the Merlin™ Patient Care System programmer based on 'Reason for Monitoring'
- Remote monitoring ready
- Patient activated and auto activated triggers for EGM storage
- Programmable data storage options to ensure capture of significant events while reducing the risk of missing unexpected events
- Proven St. Jude Medical™ Sense*Ability*™ feature designed to allow accurate sensing over a wide range of signals
- 1.5 T MR Conditional

Mobile App and Connectivity



- Bluetooth® wireless technology between ICM and myMerlin™ app which patients can download onto their mobile device. No need for a separate bulky bedside transmitter or patient activator
- ICM continuously monitors rhythm and myMerlin app proactively transmits data per schedule and alerts set by the clinic
- App features integrated activator functionality, allowing patients to privately record and transmit EGMs during symptoms. No separate activator hardware required
- Notifications inform patients of daily device checks and scheduled transmissions to promote remote monitoring adherence without burdening the clinic
- App available in 35+ languages to engage patients and provide a personalized experience
- Transmissions are sent to Merlin.net Patient Care Network providing clinicians with data review and reports
- St. Jude Medical™ mobile transmitters may be purchased for patients without their own mobile device

Ordering Information

Confirm Rx™ Insertable Cardiac Monitor

Name	Model Number	Description	MRI Status	X-ray ID Model Code
Confirm Rx™ ICM	DM3500	Insertable cardiac monitor	1.5 T MR Conditional	CC

Indications: The SJM™ Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias.

The SJM Confirm Rx ICM Model DM3500 is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

Contraindications: There are no known contraindications for the implantation of the SJM Confirm Rx™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Adverse Events: Possible adverse events (alphabetical order) associated with the use of the device include the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation and Migration. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Limitations: Patients may use their own Apple™ or Android™ mobile digital device to transmit information from their Confirm Rx™ ICM using the myMerlin™ mobile app. To do so the device must be powered on, app must be installed, Bluetooth® wireless technology connection enabled and data coverage (cellular or WiFi™) available. The myMerlin™ app provides periodic patient monitoring based on clinician configured settings. Transmission data is resent if not sent successfully. However there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of ICM and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, ICM memory capacity, clinic environment, schedule/configuration changes or data processing.

ST. JUDE MEDICAL

Product Specifications

Physical Specifications

Model	DM3500
Volume	1.4 cc nominal
Length	49 mm nominal
Width	9.4 mm nominal
Thickness	3.1 mm nominal
Weight	3.0 g nominal

Parameter	Settings
Features	
Longevity	2 years†
Detection Sampling Rate	512 Hz
Patient Trigger	Yes
Symptom Alert	Off On (All Symptoms) On (with Detection)
Remote Monitoring	myMerlin™ app via Bluetooth® wireless technology
Patient Activator	myMerlin™ app via Bluetooth® wireless technology
Tachycardia Trigger and Alert	Yes
Bradycardia Trigger and Alert	Yes
Pause Trigger and Alert	Yes
Atrial Fibrillation Trigger and Alert	Yes
Programmable AF Episode Duration	30 seconds, 1, 2, 6, 10, 20, 30, 60 minutes
AF Burden Alert	Off, 30 minutes, 1, 3, 6, 9, 12, 24 hours
AF Continuous Episode Alert	Off, 1, 2, 6, 10, 20, 30, 60, 180 minutes
Ventricular Rate during AF Alert	Off 90 – 150, 175, 200 bpm 1, 3, 6, 9, 12 hours
Activity Inhibits Auto Detection	Programmable, On or Off
Noise Response Inhibits Auto Detection	Yes
Diagnostics	
Episodal Diagnostics	Yes
Total EGM Storage	60 minutes
Symptom EGM Duration	Pre-trigger - 4, 6, 8, 10, 12, 14 minutes Post-trigger - 30, 40, 50, 60 seconds
Auto Detected EGM Duration	AF Pre and Post-Trigger - 10, 20, 30, 40, 50, 60 & 120 sec Other (Tachy, Brady, Pause) Pre and Post-Trigger – 10, 20, 30, 40, 50 & 60 secs
EGM Sampling Rate	128 Hz
Heart Rate Histogram	Yes
AF Diagnostics	Yes
AF Burden Trend	Yes

† 2 years under the following usage scenarios:
- Average of 1 auto-detected episode per day
- Average of 1 patient activated symptom per month
- Up to 6-month shelf storage time

NOTE: At a maximum shelf storage time of 18 months, longevity is reduced by approximately 5 months.

Security Measures

- The ICM encrypts its wireless communication using AES-128bit encryption and is designed to limit communications to only a single authenticated and paired myMerlin™ mobile app at any given time.
- The ICM uses a proprietary pairing protocol as an added control measure in addition to the pairing procedure specified in Bluetooth® wireless technology low energy protocols. Pairing requests are authenticated using cloud-based public key cryptography authentication.
- The ICM creates a unique 128-bit key for the paired mobile app and verifies it at the onset of every communication. If the unique key is not verified, the monitor denies access.
- The ICM uses an authorization protocol, which limits a paired mobile app's access based on clinician settings.
- The myMerlin™ mobile apps encrypt wireless communication to Merlin.net™ PCN through a secure TLS connection using SHA256 cryptographic protection.
- Merlin.net PCN is housed in a secured data center and is ISO27001:2013 certified. Access to patient data in Merlin.net PCN is restricted to authorized users as set by the clinic administrator. ICM data is encrypted using AES-128bit encryption.
- Merlin.net PCN is successfully certified through the EU-US Privacy Shield program to transfer patient information from the EU to the U.S.

Customer Support: 46-8-474-4756

SJM-CFM-0716-0011(2) 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 0249 Rev. 00

Manufacturer:

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

SRN Manufacturer: US-MF-000010382

Authorized Representative:

St. Jude Medical Coordination Center BVBA
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 0249 Rev. 00

Report No.: 713194597, 713199649

Valid from: 2021-12-13
Valid until: 2026-12-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-12-13

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

Benannt durch/Designated by
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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 0249 Rev. 00

Classification:	III
Device Group:	J01900282 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS - SOFTWARE ACCESSORY
Basic UDI-DI:	5415067CMD0001AH
Intended Purpose:	The myMerlin™ mobile application is intended for people who have a Confirm Rx™ ICM and access to a mobile device. The app allows the patient to activate recordings in the implanted device and wirelessly transmit data for physician and clinician review.
Device(s):	myMerlin™ mobile application Model No.: APP1000 (Android), APP1001 (iOS)

Classification:	III
Device Group:	J010201 - IMPLANTABLE DIAGNOSTIC ARRHYTHMIAS RECORDING CARDIAC DEVICES
Basic UDI-DI:	5415067CMD0001AH
Intended Purpose:	The Confirm Rx™ ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.
Device(s):	Confirm Rx™ Insertable Cardiac Monitor Model No.: DM3500

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

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

St. Jude Medical
Cardiac Rhythm Management Division 15900 Valley View Ct.
Sylmar, CA 91342]
Tel: +1 408 522 6464
Fax: 1-818-364-5814

16741 Rev. A

MDR Declaration of Conformity

Manufacturer:	St. Jude Medical Cardiac Rhythm Management Division
Manufacturer SRN:	US-MF-000010382
Address:	15900 Valley View Court Sylmar, CA 91342 USA
Manufacturing Site(s):	15900 Valley View Court Sylmar, CA 91342 USA St. Jude Medical Operations (M) Sdn.Bhd. Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone,11900 Penang, Malaysia
European Authorized Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008417

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

Product Type:	Implantable Monitoring and Recording Systems
Product Trade Name(s):	Confirm Rx™ myMerlin™
Model Number(s):	DM3500, APP1000, APP1001
Intended Purpose:	The Confirm Rx™ ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.

Signature: CANANCX Digitally signed by CANANCX Date: 2021.12.17 07:00:30 -08'00' Colleen Canan Senior Director Regulatory Affairs	**December 17, 2021** Issue Date On behalf of St. Jude Medical Cardiac Rhythm Management Division, signed at Sylmar, CA

St. Jude Medical
Cardiac Rhythm Management Division 15900 Valley View Ct.
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16741 Rev. A

MDR Declaration of Conformity

	The myMerlin™ mobile application is intended for people who have a Confirm Rx ICM and access to a mobile device. The app allows the patient to activate recordings in the implanted device and wirelessly transmit data for physician and clinician review.
Risk Classification:	• Confirm Rx™ ICM DM3500: Class III per EU MDR 2017/745 Annex VIII • myMerlin™ APP1000, APP1001: Class III per EU MDR 2017/745 Annex VIII
Classification Rationale:	• Confirm Rx™ ICM DM3500: Rule 8, as a long term, surgically invasive, active implantable medical device. • myMerlin™ APP1000, APP1001: Rule 11, Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause death or an irreversible deterioration of a person's state of health, in which case it is in Class III.
EMDN Code(s):	DM3500: J010201 APP1000, APP1001: J01900282
Basic UDI-DI:	5415067CMD0001AH

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:	N/A
STED #	90626180
Notified Body:	TUV Sud Product Service Ridlerstraße, 65, 80339, Münich, Germany NB #: 0123
Supporting Certificate(s):	TDAC Certificate No: G70 014607 0249 Rev. 00 Expiration Date: 2026-12-12 QMS Certificate No: G12 014607 0244 Rev. 01 Expiration Date: 2026-04-06

The signature is applied on page 1

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16741 Rev. A

MDR Declaration of Conformity

Original CE Mark Date:	Device Name	Original CE Mark Date (AIMDD)
	Confirm Rx™ - Insertable Cardiac Monitor DM3500	December 16, 2016
	myMerlin™ mobile application APP1000 (Android)	December 16, 2016
	myMerlin™ mobile application APP1001 (iOS)	April 06, 2017
Conformity Assessment:	Annex IX	
Device Photograph:	Figure 1: Confirm Rx™ ICM DM3500 Picture, Figure 2: Confirm Rx™ ICM DM3500 Packaging Configuration, Picture	

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. Bucatului 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.