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. C

# MDR Declaration of Conformity

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

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

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| **Product Type:** | Implantable Monitoring and Recording Systems |
| **Product Trade Name(s):** | Confirm Rx™<br>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. |

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| **Signature:** CANANCX Digitally signed by CANANCX Date: 2022.04.18 16:25:07 -07'00'<br>_____<br>Colleen Canan<br>Divisional Vice President Regulatory Affairs | **April 18, 2022**<br>_____<br>Issue Date<br><br>On behalf of St. Jude Medical Cardiac Rhythm Management Division, signed at Sylmar, CA |

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| | 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<br>• 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.<br>• 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<br>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

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| **Common Specifications Applied:** | N/A |
| **STED #** | 90626180 |
| **Notified Body:** | TÜV SÜD Product Service GmbH<br>Ridlerstraße 65, 80339 Munich, Germany<br>NB #: 0123 |
| **Supporting Certificate(s):** | TDAC Certificate No: G70 014607 0249 Rev. 00<br>Expiration Date: 2026-12-12<br><br>QMS Certificate No: G12 014607 0244 Rev. 02<br>Expiration Date: 2026-04-06 |

The signature is applied on page 1

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| **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,<br>Figure 2: Confirm Rx™ ICM DM3500 Packaging Configuration, Picture | |

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**Figure 1: Confirm Rx™ ICM DM3500, Picture**

**Figure 2: Confirm Rx™ ICM DM3500, Packaging Configuration with IC preloaded in Insertion Tool**

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# MDR Declaration of Conformity

The products in the attached Declaration of Conformity Product List are approved under EC Certificate No. G70 014607 0249 Rev. 00.

**Declaration of Conformity Product List**

| Model No. | Description | UDI-DI |
|---|---|---|
| DM3500 | Confirm Rx™ Insertable Cardiac Monitor | 05415067027320 |
| APP1000 (Android) | myMerlin™ mobile application | 05415067027399 |
| APP1001 (iOS) | myMerlin™ mobile application | 05415067027405 |