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TÜV SÜD Product Service

# EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0238 Rev. 00**

**Manufacturer:**

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

**Product:**

**Implantable Cardioverter / Defibrillator Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

**Report no.:** 713171090

**Valid from:** 2019-12-11
**Valid until:** 2024-05-26

**Date,** 2019-12-11

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

**No. I7 014607 0238 Rev. 00**

**Model(s):** **see below**

**Facility(ies):**

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

St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo PR 00612, USA

St. Jude Medical Operations (M) Sdn.Bhd.
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA

**Design Facility(ies):**

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

**Product:** **Implantable Cardioverter / Defibrillators**

Test Report No.: 713171090_1

| **Model:** | **Model no.:** | **Variant:** |
|---|---|---|
| Avant™ VR | CDVRA700Q | MR Conditional |
| Gallant™ VR | CDVRA500Q | MR Conditional |
| Entrant™ VR | CDVRA300Q | MR Conditional |
| Neutrino™ NxT VR | CDVRA800Q | MR Conditional |
| Neutrino™ NxT VR | CDVRA600Q | MR Conditional |
| Avant™ DR | CDDRA700Q | MR Conditional |
| Gallant™ DR | CDDRA500Q | MR Conditional |
| Entrant™ DR | CDDRA300Q | MR Conditional |


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TÜV SÜD Product Service

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**No. I7 014607 0238 Rev. 00**

| | | |
|---|---|---|
| Neutrino™ NxT DR | CDDRA800Q | MR Conditional |
| Neutrino™ NxT DR | CDDRA600Q | MR Conditional |
| Avant™ HF | CDHFA700Q | MR Conditional |
| Gallant™ HF | CDHFA500Q | MR Conditional |
| Entrant™ HF | CDHFA300Q | MR Conditional |
| Neutrino™ NxT HF | CDHFA800Q | MR Conditional |
| Neutrino™ NxT HF | CDHFA600Q | MR Conditional |

**Product:** **Patient Mobile Application**

Test Report No.: 713171090_2

| **Model:** | **Model no.:** | **Variant:** |
|---|---|---|
| myMerlinPulse™ | APP1004 | Android |
| myMerlinPulse™ | APP1005 | iOS |


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