ST. JUDE MEDICAL

RED Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following product(s) conform to the applicable provisions of the Radio Equipment Directive (2014/53/EU). All supporting documentation is retained under the premises of SJM. 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:	Implantable Cardioverter/Defibrillators
Applicable Standards:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Applicable Annex:	II
Technical Construction File:	60085281

Signature:

T.J. Huble

Theodore J. Huble
Senior Director of Development Quality
Plymouth, MN 55442

24 MAY 2017
Issue Date

RED Declaration of Conformity

Product Name (s)	Model #	Description of accessories and components:
Ellipse™ VR	CD1275-36	NA
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	NA
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	NA
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Декларация за съответствие съгласно Директивата за радиосъоръженията

С настоящото St. Jude Medical (SJM) декларира, че следният(те) продукт(и) е в съответствие с приложимите разпоредби на Директива 2014/53/ЕС за хармонизирането на законодателствата на държавите членки във връзка с предоставянето на пазара на радиосъоръжения. Цялата съпътстваща документация се съхранява на територията на SJM. Настоящата декларация се издава изцяло на отговорността на производителя. Настоящата декларация заменя всички предходно издадени декларации за същия(те) продукт(и).

Адрес на производителя:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, САЩ
Европейски представител	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Белгия
Вид на продукта:	Имплантируем кардиовертер/дефибрилатори
Приложими стандарти:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EO EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Приложимо приложение:	II
Техническо досие:	60085281

Подписът е положен на стр. 1.

Декларация за съответствие съгласно Директивата за радиосъоръженията

Наименование на продукта(и)	Модел №	Описание на принадлежности и компоненти:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	NA
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	NA
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	NA

Izjava o usklađenosti s Direktivom o radijskoj opremi (RED)

St. Jude Medical (SJM) ovime izjavljuje da sljedeći proizvodi zadovoljavaju važeće odredbe Direktive o radijskoj opremi (2014/53/EU). Sva popratna dokumentacija čuva se na lokaciji tvrtke SJM. Ova se izjava daje pod isključivom odgovornošću proizvođača. Ova izjava nadjačava sve prethodne izjave za iste proizvode.

Adresa proizvođača:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Predstavnik u Europi:	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium
Vrsta proizvoda:	implantibilni kardioverter/defibrilatori
Primjenjive norme:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EZ EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Primjenjivi dodatak:	II
Tehnička mapa:	60085281

Potpis se odnosi na 1. stranicu.

Izjava o usklađenosti s Direktivom o radijskoj opremi (RED)

Nazivi proizvoda	Broj modela	Opis pribora i komponenti:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	nije primjenjivo
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	nije primjenjivo
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	nije primjenjivo

Prohlášení o shodě dle směrnice 2014/53/EU

St. Jude Medical (SJM) tímto prohlašuje, že následující výrobky splňují příslušná ustanovení směrnice o harmonizaci právních předpisů členských států týkajících se dodávání rádiových zařízení na trh (2014/53/EU). Veškerá podpůrná dokumentace se nachází v prostorách SJM. Toto prohlášení se vydává na výhradní odpovědnost výrobce. Tímto prohlášením se nahrazuje jakékoli prohlášení vystavené ke stejným výrobkům dříve.

Adresa výrobce:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Zástupce v Evropské unii	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgie
Typ výrobku:	Implantační kardioverter/defibrilátory
Příslušné normy:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Příslušná příloha:	II
Technický konstrukční soubor:	60085281

Podpis je uveden na straně 1.

Prohlášení o shodě dle směrnice 2014/53/EU

Název výrobku (výrobků)	Č. modelu	Popis příslušenství a součástí:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	—
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	—
Unify™ Unify™ CRT-D Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	—

RED Overensstemmelseserklæring

St. Jude Medical (SJM) erklærer hermed, at følgende produkt(er) overholder de relevante bestemmelser i radioudstyrsdirektivet (2014/53/EU). Al understøttende dokumentation tilhører SJM. Nærværende erklæring udstedes alene under producentens ansvar. Nærværende erklæring tilsidesætter alle tidligere udstedte erklæringer for samme produkt(er).

Producentens adresse:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Europæisk repræsentant	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgien
Produkttype:	Implanterbare cardioverter/defibrillatorer
Gældende standarder:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Gældende bilag:	II
Teknisk konstruktionsfil:	60085281

Signatur på side 1.

RED Overensstemmelseserklæring

Produktnavn(e)	Modelnummer	Beskrivelse af tilbehør og komponenter:
Ellipse™ VR	CD1275-36	Ikke relevant
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Ikke relevant
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Ikke relevant
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Conformiteitsverklaring Richtlijn voor radioapparatuur

St. Jude Medical (SJM) verklaart hierbij dat de volgende producten voldoen aan de toepasselijke bepalingen van de Richtlijn voor radioapparatuur (2014/53/EU). Alle ondersteunende documentatie wordt bewaard op het terrein van SJM. Deze verklaring is onder de volledige verantwoordelijkheid van de fabrikant uitgegeven. Deze verklaring vervangt alle verklaringen die eerder voor deze producten zijn uitgegeven.

Adres fabrikant:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, VS
Europese vertegenwoordiger	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, België
Producttype:	Implanteerbare cardioverter/defibrillator
Toepasselijke normen:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Toepasselijke bijlage:	II
Technisch constructiebestand:	60085281

De handtekening is op pagina 1 gezet.

Conformiteitsverklaring Richtlijn voor radioapparatuur

Productnaam/-namen	Modelnr.	Beschrijving van accessoires en onderdelen:
Ellipse™ VR	CD1275-36	N.v.t.
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	N.v.t.
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	N.v.t.
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Raadioseadmete direktiivi kohane vastavusdeklaratsioon

St. Jude Medical (SJM) kinnitab, et järgmine toode või järgmised tooted vastavad raadioseadmete direktiivi (2014/53/EL) kohaldatavatele sätetele. Kõik tõendavad dokumendid säilitatakse SJM-is. See deklaratsioon on välja antud tootja ainuvastutusel. See deklaratsioon asendab kõik eelnevad selle toote või nende toodete kohta välja antud deklaratsioonid.

Tootja aadress:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, Ameerika Ühendriigid
Esindaja Euroopas	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgia
Toote tüüp:	Implanteeritavad kardioverter-defibrillaatorid
Kohaldatavad standardid:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Kohaldatav lisa:	II
Tehnilise projekteerimise fail:	60085281

Allkirjastatud on esimene lehekülg.

Raadioseadmete direktiivi kohane vastavusdeklaratsioon

Toote nimi/nimed	Mudeli nr	Tarvikute ja komponentide kirjeldus:
Ellipse™ VR	CD1275-36	Ei ole kohaldatav
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Ei ole kohaldatav
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Ei ole kohaldatav
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

RED-vaatimustenmukaisuusvakuutus

St. Jude Medical (SJM) vakuuttaa täten, että seuraavat tuotteet noudattavat radiolaitedirektiivin (RED) (2014/53/EU) soveltuvia säännöksiä. Kaikkia täydentäviä asiakirjoja säilytetään SJM:n tiloissa. Tämä vakuutus on annettu yksinomaan valmistajan vastuulla. Tämä vakuutus korvaa kaikki aiemmin samoista tuotteista annetut vakuutukset.

Valmistajan osoite:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Edustaja Euroopassa:	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgia
Tuotetyyppi:	Implantoitava rytmihäiriöntahdistin/defibrillaattori
Sovellettavat standardit:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EY EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Sovellettavat liitteet:	II
Tekninen rakennetiedosto:	60085281

Allekirjoitus tulee 1. sivulle.

RED-vaatimustenmukaisuusvakuutus

Tuotenimi (tuotenimet)	Mallinro	Lisävarusteiden ja osien kuvaus:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	–
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	–
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	–

Déclaration de conformité RED

St. Jude Medical (SJM) déclare par la présente que le ou les produits suivants satisfont aux dispositions applicables de la Directive relative aux équipements radioélectriques (2014/53/EU). L'ensemble des documents justificatifs est conservé dans les locaux de SJM. Cette déclaration est établie sous la seule responsabilité du fabricant. Cette déclaration annule toute déclaration précédemment établie pour le ou les mêmes produits.

Adresse du fabricant :	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, États-Unis
Représentant européen	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgique
Type de produit :	Défibrillateurs/cardioverteur implantables
Normes applicables :	3.1a : EN 62311:2008, EN 62479:2010, SAR: 1999/519/CE EN 45502-1:2015, EN 45502-2-2:2008, ISO 14708-6:2010, ISO 14117:2012 3.1b : EN 45502-1:2015, EN45502-2-2:2008, CEI 60601-1-2:2015, ISO 14117:2012 3.2 : EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Annexe applicable :	II
Dossier technique de construction :	60085281

La signature se trouve en page 1.

Déclaration de conformité RED

Nom du produit/des produits	Référence #	Description des accessoires et des composants :
Ellipse™ VR	CD1275-36	Nd
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Nd
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Nd
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Funkanlagen-Konformitätserklärung

St. Jude Medical (SJM) erklärt hiermit, dass das folgende Produkt / die folgenden Produkte den anwendbaren Vorschriften der Richtlinie 2014/53/EU zur Bereitstellung von Funkanlagen entsprechen. Jedwede Belegunterlagen werden auf dem Firmengelände von SJM aufbewahrt. Der Hersteller trägt die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung. Diese Erklärung ersetzt jedwede Erklärung, die vorher für dasselbe Produkt / dieselben Produkte ausgestellt wurde.

Anschrift des Herstellers:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Europäische Vertretung:	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgien
Produkttyp:	Implantierbare Kardioverter-Defibrillatoren
Relevante Normen:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EG EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Relevante Anhänge:	II
Technische Dokumentation:	60085281

Die Signatur wird auf Seite 1 eingesetzt.

Funkanlagen-Konformitätserklärung

Produktname(n)	Modell-Nr.	Beschreibung des Zubehörs und der Komponenten:
Ellipse™ VR	CD1275-36	-
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	-
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	-
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Δήλωση συμμόρφωσης RED

Με το παρόν, η St. Jude Medical (SJM) δηλώνει ότι τα παρακάτω προϊόντα συμμορφώνονται προς τις ισχύουσες διατάξεις της Οδηγίας περί ραδιοεξοπλισμού (2014/53/ΕΕ). Όλη η τεκμηρίωση διατηρείται στις εγκαταστάσεις της SJM. Η παρούσα δήλωση εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή. Η παρούσα δήλωση αντικαθιστά οποιαδήποτε δήλωση έχει εκδοθεί για το ίδιο προϊόν/τα ίδια προϊόντα.

Διεύθυνση κατασκευαστή:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, ΗΠΑ
Αντιπρόσωπος για την Ευρώπη	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Βέλγιο
Τύπος προϊόντος:	Εμφυτεύσιμοι καρδιομετατροπείς/απινιδωτές
Ισχύοντα πρότυπα:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Ισχύον παράρτημα:	II
Αρχείο τεχνικής κατασκευής:	60085281

Η υπογραφή εφαρμόζεται στη σελίδα 1.

Δήλωση συμμόρφωσης RED

Ονομασία προϊόντος (ων)	Αρ. μοντέλου	Περιγραφή παρελκομένων και εξαρτημάτων:
Ellipse™ VR	CD1275-36	Δεν ισχύει
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Δεν ισχύει
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Δεν ισχύει
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

A rádióberendezésekről szóló irányelv szerinti megfelelőségi nyilatkozat

A St. Jude Medical (SJM) ezennel kijelenti, hogy a következő termék(ek) megfelel(nek) az EU rádióberendezésekről szóló irányelve (2014/53/EU) vonatkozó rendelkezéseinek. Az ezt alátámasztó teljes dokumentációt az SJM a saját területén tárolja. E nyilatkozat kiadása kizárólag a gyártó felelősségére történik. Ez a nyilatkozat felülír minden korábbi, ugyanezekre a termékekre vonatkozó nyilatkozatot.

A gyártó címe:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Európai képviselő	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium
Termék típusa:	Beültethető kardioverter/defibrillátorok
Vonatkozó szabványok:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Vonatkozó melléklet:	II
A műszaki felépítést tartalmazó fájl:	60085281 hó

Az aláírás az 1. oldalon található.

A rádióberendezésekről szóló irányelv szerinti megfelelőségi nyilatkozat

A termék(ek) neve(i)	Típusszám	A tartozékok és összetevők leírása:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	Nem értelmezhető
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	Nem értelmezhető
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	Nem értelmezhető

Dichiarazione di conformità a RED

Con la presente, St. Jude Medical (SJM) dichiara che il/i seguente/i prodotto/i è/sono conforme/i alle disposizioni applicabili della direttiva 2014/53/UE concernente l'armonizzazione delle legislazioni degli Stati membri relative alla messa a disposizione sul mercato di apparecchiature radio. Tutta la documentazione di supporto è conservata sotto la responsabilità di SJM. La presente dichiarazione è rilasciata sotto la responsabilità esclusiva del produttore. La presente dichiarazione sostituisce ogni dichiarazione rilasciata in precedenza per lo/gli stesso/i prodotto/i.

Indirizzo del produttore:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Rappresentante per l'Unione europea:	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgio
Tipo di prodotto:	Dispositivi di cardioversione/defibrillazione impiantabili
Norme applicabili:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/CE EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Allegato applicabile:	II
Fascicolo tecnico di fabbricazione:	60085281

La firma è applicata a pag. 1.

Dichiarazione di conformità a RED

Nome dei prodotti	N. modello	Descrizione di accessori e componenti:
Ellipse™ VR	CD1275-36	N/D
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	N/D
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	N/D
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

RED Atbilstības deklarācija

Ar šo St. Jude Medical (turpmāk — SJM) apstiprina, ka zemāk norādītie izstrādājumi atbilst piemērojamajām prasībām ES direktīvā attiecībā uz radioiekārtu pieejamību tirgū (2014/53/ES). Visi apstiprinošie dokumenti tiek glabāti SJM telpās. Par šīs deklarācijas izdošanu atbildīgs ir tikai ražotājs. Šī deklarācija aizstāj jebkuru citu deklarāciju, kas iepriekš izdota par šo(-iem) izstrādājumu(-iem).

Ražotāja adrese:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, ASV
Pārstāvis Eiropas Savienībā	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Beļģija
Izstrādājuma veids:	Implantējami kardioverteri un defibrilatori
Piemērojamie standarti:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EK EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Piemērojamais pielikums:	II
Tehniskā konstrukcijas dokumentācija:	60085281

Paraksts atrodas 1. lpp.

RED Atbilstības deklarācija

Izstrādājuma nosaukums(-i)	Modeļa nr.	Piederumu un sastāvdaļu apraksts
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	Nav piemērojams
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	Nav piemērojams
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	Nav piemērojams

Direktyvoje dėl radijo įrangos pateiktų reikalavimų atitikties deklaracija

„St. Jude Medical“ (SJM) pareiškia, kad toliau nurodyti gaminiai atitinka taikytinas direktyvos dėl valstybių narių įstatymų, susijusių su radijo įrenginių tiekimu rinkai, suderinimo (2014/53/ES) nuostatas. Visi pagrindžiantys dokumentai saugomi SJM patalpose. Už šios deklaracijos leidimą visą atsakomybę prisiima gamintojas. Ši deklaracija panaikina anksčiau išleistas tų pačių gaminių deklaracijas.

Gamintojo adresas	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, JAV
Atstovas Europoje	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgija
Gaminio tipas	Implantuojamas kardiostimuliatorius / defibriliatorius
Taikytini standartai	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EB EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 2.1.1 vers. (2016-06) EN 300 328 2.1.1 vers. (2016-11) EN 301 839 2.1.1 vers. (2016-04)
Taikytinas priedas	II
Techninis failas	60085281

Pasirašoma 1 psl.

Direktyvoje dėl radijo įrangos pateiktų reikalavimų atitikties deklaracija

Gaminio pavadinimas	Modelio Nr.	Priedų ir komponentų aprašas
Ellipse™ VR	CD1275-36	Nėra
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1 / DF-1	CD1377-36	
Ellipse™ VR IS-1 / DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1 / DF-1	CD2377-36	
Ellipse™ DR IS-1 / DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Nėra
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1 / DF-1	CD1359-40	
Fortify Assura™ VR IS-1 / DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1 / DF-1	CD2359-40	
Fortify Assura™ DR IS-1 / DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Nėra
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1 / DF-1	CD3361-40	
Unify Assura™ IS-1 / DF-1	CD3361-40C	
Unify Assura™ IS-1 / DF-1	CD3361-40Q	
Unify Assura™ IS-1 / DF-1	CD3361-40QC	
Quadra Assura™ IS-1 / DF-1	CD3367-40	
Quadra Assura™ IS-1 / DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1 / DF-1	CD3371-40	
Quadra Assura MP™ IS-1 / DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Deklaracja zgodności RED

Firma St. Jude Medical (SJM) niniejszym oświadcza, że następujące produkty są zgodne ze stosownymi przepisami dyrektywy Parlamentu Europejskiego i Rady w sprawie harmonizacji ustawodawstw państw członkowskich dotyczących udostępniania na rynku urządzeń radiowych (2014/53/UE). Cała dokumentacja uzupełniająca jest przechowywana w siedzibie firmy SJM. Niniejsza deklaracja jest wydawana na wyłączną odpowiedzialność producenta. Deklaracja ta zastępuje wszystkie deklaracje wydane wcześniej dla tych samych produktów.

Adres producenta:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Przedstawiciel w Unii Europejskiej:	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgia
Typ produktu:	Implantowalne kardiowertery/defibrylatory
Obowiązujące normy:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Obowiązujący załącznik:	II
Dokumentacja techniczno-konstrukcyjna:	60085281

Podpis składa się na stronie 1.

Deklaracja zgodności RED

Nazwa (nazwy) produktu	Nr modelu	Opis akcesoriów i elementów:
Ellipse™ VR	CD1275-36	Nie dotyczy
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Nie dotyczy
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Nie dotyczy
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

RED — Declaração de conformidade

A St. Jude Medical (SJM) declara que o(s) seguinte(s) produto(s) está(ão) em conformidade com as disposições aplicáveis da diretiva respeitante à disponibilização de equipamentos de rádio no mercado (2014/53/UE). Todos os documentos comprovativos são mantidos nas instalações da SJM. A presente declaração de conformidade é emitida sob a exclusiva responsabilidade do fabricante. Esta declaração substitui qualquer declaração formulada anteriormente para o(s) mesmo(s) produto(s).

Endereço do fabricante:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, EUA
Representante europeu:	St.Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Bélgica
Tipo de produto:	Cardioversores/desfibrilhadores implantáveis
Normas aplicáveis:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/CE EN 45502-1:2015, EN 45502-2-2:2008, ISO 14708-6:2010, ISO 14117:2012 3.1b: EN 45502-1:2015, EN 45502-2-2:2008, IEC 60601-1-2:2015, ISO 14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Anexo aplicável:	II
Dossier técnico de construção:	60085281

A assinatura é aplicada na página 1.

RED — Declaração de conformidade

Nome(s) do produto	N.º de modelo	Descrição de acessórios e componentes:
Ellipse™ VR	CD1275-36	N/D
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	N/D
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	N/D
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Declarație de conformitate cu Directiva privind echipamentele radio

Prin prezenta, St. Jude Medical (SJM) declară că produsele prezentate în continuare sunt în conformitate cu prevederile aplicabile ale Directivei privind echipamentele radio (2014/53/UE). Toate documentele justificative sunt păstrate la sediul SJM. Această declarație este emisă pe răspunderea exclusivă a producătorului. Această declarație înlocuiește orice altă declarație emisă anterior pentru aceleași produse.

Adresă producător:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, SUA
Reprezentant european	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgia
Tip produs:	Defibrilatoare/cardioconvertoare implantabile
Standarde aplicabile:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/CE EN 45502-1:2015, EN 45502-2-2:2008, ISO 14708-6:2010, ISO 14117:2012 3.1b: EN 45502-1:2015, EN 45502-2-2:2008, IEC 60601-1-2:2015, ISO 14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Anexă aplicabilă:	II
Dosar de construcție tehnică:	60085281

Documentul se semnează pe pagina 1.

Declarație de conformitate cu Directiva privind echipamentele radio

Nume produs	Număr model	Descrierea accesoriilor și a componentelor:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	Nu este cazul
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	Nu este cazul
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	Nu este cazul

Vyhlásenie o zhode so smernicou o rádiových zariadeniach

Spoločnosť St. Jude Medical (SJM) týmto vyhlasuje, že uvedené výrobky spĺňajú platné ustanovenia Smernice Európskeho parlamentu a Rady 2014/53/EÚ o harmonizácii právnych predpisov členských štátov týkajúcich sa sprístupňovania rádiových zariadení na trhu. Všetka podporná dokumentácia sa uchováva v priestoroch spoločnosti SJM. Toto vyhlásenie sa vydáva na výhradnú zodpovednosť výrobcu. Toto vyhlásenie nahrádza akékoľvek iné predtým vydané vyhlásenie týkajúce sa tých istých výrobkov.

Adresa výrobcu:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Európsky zástupca:	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgicko
Typ výrobku:	Implantovateľné kardiovertery/defibrilátory
Platné normy:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/ES EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Platná príloha:	II
Súbor technickej konštrukčnej dokumentácie:	60085281

Podpis sa uvádza na strane 1.

Vyhlásenie o zhode so smernicou o rádiových zariadeniach

Názov výrobku	Č. modelu	Popis príslušenstva a súčastí:
Ellipse™ VR	CD1275-36	Neuvádza sa
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Neuvádza sa
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Neuvádza sa
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Izjava o skladnosti z Direktivo o radijski opremi

Podjetje St. Jude Medical (SJM) izjavlja, da so naslednji izdelki skladni z veljavnimi določili Direktive o radijski opremi (2014/53/EU). Vso podporno dokumentacijo hrani podjetje SJM. Za izdajo te izjave je izključno odgovoren izdelovalec. Ta izjava nadomesti vse predhodne izjave, ki so bile izdane za iste izdelke.

Naslov izdelovalca:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, ZDA
Zastopnik za Evropo:	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgija
Vrsta izdelka:	Vsadni kardioverter/defibrilatorji
Veljavni standardi:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/ES EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Veljavni dodatek:	II.
Tehnična dokumentacija:	60085281

Podpis je na 1. strani.

Izjava o skladnosti z Direktivo o radijski opremi

Ime izdelka/-ov:	Št. modela:	Opis sestavnih delov in dodatne opreme:
Ellipse™ VR	CD1275-36	Se ne uporablja.
Ellipse™ VR	CD1275-36Q	
Ellipse™ VR IS-1/DF-1	CD1377-36	
Ellipse™ VR IS-1/DF-1	CD1377-36C	
Ellipse™ VR DF-4	CD1377-36Q	
Ellipse™ VR DF-4	CD1377-36QC	
Ellipse™ DR	CD2275-36	
Ellipse™ DR	CD2275-36Q	
Ellipse™ DR IS-1/DF-1	CD2377-36	
Ellipse™ DR IS-1/DF-1	CD2377-36C	
Ellipse™ DR DF-4	CD2377-36Q	
Ellipse™ DR DF-4	CD2377-36QC	
Fortify™ VR	CD1233-40	Se ne uporablja.
Fortify™ VR	CD1233-40Q	
Fortify Assura™ VR IS-1/DF-1	CD1359-40	
Fortify Assura™ VR IS-1/DF-1	CD1359-40C	
Fortify Assura™ VR DF-4	CD1359-40Q	
Fortify Assura™ VR DF-4	CD1359-40QC	
Fortify™ DR	CD2233-40	
Fortify™ DR	CD2233-40Q	
Fortify Assura™ DR IS-1/DF-1	CD2359-40	
Fortify Assura™ DR IS-1/DF-1	CD2359-40C	
Fortify Assura™ DR DF-4	CD2359-40Q	
Fortify Assura™ DR DF-4	CD2359-40QC	
Unify™	CD3235-40	Se ne uporablja.
Unify™	CD3235-40Q	
Unify Quadra™	CD3251-40	
Unify Quadra™	CD3251-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40	
Unify Assura™ IS-1/DF-1	CD3361-40C	
Unify Assura™ IS-1/DF-1	CD3361-40Q	
Unify Assura™ IS-1/DF-1	CD3361-40QC	
Quadra Assura™ IS-1/DF-1	CD3367-40	
Quadra Assura™ IS-1/DF-1	CD3367-40C	
Quadra Assura™ DF-4	CD3367-40Q	
Quadra Assura™ DF-4	CD3367-40QC	
Quadra Assura MP™ IS-1/DF-1	CD3371-40	
Quadra Assura MP™ IS-1/DF-1	CD3371-40C	
Quadra Assura MP™ DF-4	CD3371-40Q	
Quadra Assura MP™ DF-4	CD3371-40QC	

Declaración de conformidad con la Directiva sobre equipos radioeléctricos

Por la presente, St. Jude Medical (SJM) declara que el siguiente producto cumple con las disposiciones aplicables de la Directiva sobre equipos radioeléctricos (2014/53/UE). Toda la documentación de apoyo se conserva en las instalaciones de SJM. Esta declaración se expide bajo la exclusiva responsabilidad del fabricante. La presente declaración sustituye cualquier otra divulgada anteriormente para el mismo producto.

Dirección del fabricante:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, EE. UU.
Representante en Europa	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Bélgica
Tipo de producto:	Desfibriladores o cardioversores implantables
Normas aplicables:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/CE EN 45502-1:2015, EN 45502-2-2:2008, ISO 14708-6:2010, ISO 14117:2012 3.1b: EN 45502-1:2015, EN 45502-2-2:2008, IEC 60601-1-2:2015, ISO 14117:2012 3.2: EN 302 195 V2.1.1 (06-2016) EN 300 328 V2.1.1 (11-2016) EN 301 839 V2.1.1 (04-2016)
Anexo aplicable:	II
Archivo de construcción técnica:	60085281

La firma se estampa en la página 1.

Declaración de conformidad con la Directiva sobre equipos radioeléctricos

Nombre del producto	N.º de modelo	Descripción de los accesorios y componentes
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	ND
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	ND
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	ND

Försäkran om överensstämmelse med radioutrustningsdirektivet

St. Jude Medical (SJM) försäkrar härmed att följande produkt(er) uppfyller de tillämpliga kraven i Europaparlamentets och rådets direktiv om harmonisering av medlemsstaternas lagstiftning om tillhandahållande på marknaden av radioutrustning (2014/53/EU). All styrkande dokumentation finns tillgänglig hos SJM. Denna försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar. Denna försäkran ersätter varje tidigare försäkran som har utfärdats för samma produkt(er).

Tillverkarens adress:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, USA
Europeisk representant	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgien
Produkttyp:	Implanterbar elkonverterare-defibrillator
Tillämpliga standarder:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
Tillämplig bilaga:	II
Teknisk dokumentation:	60085281

Signatur på sidan 1.

Försäkran om överensstämmelse med radioutrustningsdirektivet

Produktnamn	Modellnr	Beskrivning av tillbehör och komponenter:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	Ej tillämpligt
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	Ej tillämpligt
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	Ej tillämpligt

RED Uyumluluk Beyanı

St. Jude Medical (SJM), işbu belge ile şu ürünlerin Radyo Ekipmanları Direktifinin (2014/53/EU) ilgili hükümlerine uygun olduğunu beyan eder. Tüm destekleyici belgeler SJM şirketinde tutulmaktadır. İşbu beyan, yalnızca üreticinin sorumluluğu altında çıkarılmıştır. İşbu beyan, aynı ürünler için daha önce çıkarılmış beyanların yerine geçer.

Üreticinin Adresi:	St. Jude Medical Cardiac Rhythm Management Division, 15900 Valley View Court, Sylmar, CA 91342, ABD
Avrupa Temsilcisi	St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belçika
Ürün Türü:	İmplante Edilebilir Kardiyoverter/Defibrilatörler
İlgili Standartlar:	3.1a: EN 62311:2008, EN 62479:2010, SAR: 1999/519/EC EN 45502-1:2015, EN 45502-2-2:2008, ISO14708-6:2010, ISO14117:2012 3.1b: EN 45502-1:2015, EN45502-2-2:2008, IEC 60601-1-2:2015, ISO14117:2012 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.1.1 (2016-11) EN 301 839 V2.1.1 (2016-04)
İlgili Ek:	II
Teknik Yapı Dosyası:	60085281

Sayfa 1 imzalanmıştır.

RED Uyumluluk Beyanı

Ürün Adları	Model No	Aksesuar ve bileşenlerin açıklaması:
Ellipse™ VR Ellipse™ VR Ellipse™ VR IS-1/DF-1 Ellipse™ VR IS-1/DF-1 Ellipse™ VR DF-4 Ellipse™ VR DF-4 Ellipse™ DR Ellipse™ DR Ellipse™ DR IS-1/DF-1 Ellipse™ DR IS-1/DF-1 Ellipse™ DR DF-4 Ellipse™ DR DF-4	CD1275-36 CD1275-36Q CD1377-36 CD1377-36C CD1377-36Q CD1377-36QC CD2275-36 CD2275-36Q CD2377-36 CD2377-36C CD2377-36Q CD2377-36QC	Geçerli Değil
Fortify™ VR Fortify™ VR Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR IS-1/DF-1 Fortify Assura™ VR DF-4 Fortify Assura™ VR DF-4 Fortify™ DR Fortify™ DR Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR IS-1/DF-1 Fortify Assura™ DR DF-4 Fortify Assura™ DR DF-4	CD1233-40 CD1233-40Q CD1359-40 CD1359-40C CD1359-40Q CD1359-40QC CD2233-40 CD2233-40Q CD2359-40 CD2359-40C CD2359-40Q CD2359-40QC	Geçerli Değil
Unify™ Unify™ Unify Quadra™ Unify Quadra™ Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Unify Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ IS-1/DF-1 Quadra Assura™ DF-4 Quadra Assura™ DF-4 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ IS-1/DF-1 Quadra Assura MP™ DF-4 Quadra Assura MP™ DF-4	CD3235-40 CD3235-40Q CD3251-40 CD3251-40Q CD3361-40 CD3361-40C CD3361-40Q CD3361-40QC CD3367-40 CD3367-40C CD3367-40Q CD3367-40QC CD3371-40 CD3371-40C CD3371-40Q CD3371-40QC	Geçerli Değil