



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-200.14.03



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 0194 Rev. 01

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

Product: **Leads for Tachy IPGs and their auxiliary components**

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.: 713168380

Valid from: 2020-03-04

Valid until: 2024-05-26

Date, 2020-03-04

Christoph Dicks
 Head of Certification/Notified Body

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



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No. I7 014607 0194 Rev. 01

Model(s): see below

Product: Leads for Tachy IPGs and their auxiliary components

Test Report No.: 713050175, 71326511

Model:	Model no.:	Length [cm]:	Variant:
Durata™	7120	60	
		65	
		75	
	7121	60	
		65	
		75	
	7122	60	
		65	
		75	
	7170	60	
		65	
		75	
	7171	60	
		65	
		75	

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No. I7 014607 0194 Rev. 01

Test Report No.: 713050175, 71327993, 713057341

Model:	Model no.:	Length [cm]:	Variant:
Durata™	7120Q	52	
		58	MR Conditional
		65	MR Conditional
	7121Q	52	
		58	
		65	
	7122Q	52	
		58	MR Conditional
		65	MR Conditional
	7170Q	52	
		58	
		65	
	7171Q	52	
		58	
		65	
	7172Q	52	
		58	
		65	

Test Report No.: 713050175, 713015987_2

Model:	Model no.:	Length [cm]:	Variant:
Optisure™	LDA220	60	
		65	
		75	
	LDA230	60	
		65	
		75	

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

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LDA210	60 65 75
LDP220	60 65 75
LDP230	60 65 75

Test Report No.: 713050175, 713015987_2, 713057341

Model:	Model no.:	Length [cm]:	Variant:
Optisure™	LDA220Q	52	MR Conditional MR Conditional
		58	
		65	
LDA230Q	LDA230Q	52	MR Conditional MR Conditional
		58	
		65	
LDA210Q	LDA210Q	52	MR Conditional MR Conditional
		58	
		65	
LDP220Q	LDP220Q	52	
		58	
		65	
LDP230Q	LDP230Q	52	
		58	
		65	
LDP210Q	LDP210Q	52	
		58	
		65	

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