



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 039709 1199 Rev. 01

Manufacturer:

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis MN 55432
USA

EC-Representative:

Medtronic B.V.

Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

Product:

Implantable Pacemaker 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.:

713127272

Valid from:

2019-06-17

Valid until:

2023-09-29

Date,

2019-06-17

Stefan Preiß



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 039709 1199 Rev. 01

Model(s):

see below

Facility(ies):

Medtronic Inc.

8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Puerto Rico Operations Co., Juncos

Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR
00777, USA

Medtronic Europe Sàrl

Route du Molliou 31, Case Postale, 1131 Tolochenaz,
SWITZERLAND

Medtronic Singapore Operations Pte. Ltd.

49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056,
SINGAPORE

Design Facility(ies):

Medtronic Inc.

8200 Coral Sea St., Mounds View MN 55112, USA

Parameters:

./.

Implantable Pacemaker System: SureScan™

Product: Implantable Pacemaker

Test Report No.: 71350692

Model:

Advisa DR MRI™ SureScan™

Model No:

A3DR01

Variant:

MR Conditional

Test Report No.: 71366167

Model:

Ensura DR MRI™ SureScan™

Model No:

EN1DR01

Variant:

MR Conditional

Test Report No.: 713039269

Model:

Advisa SR MRI™ SureScan™

Model No:

A3SR01

Variant:

MR Conditional

Ensura SR MRI™ SureScan™

EN1SR01

MR Conditional

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 039709 1199 Rev. 01

Product: Application Software (external)

Test Report No.: 71338901

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW005	2090	EnRhythm EMDR01

Test Report No.: 71351141

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090	Advisa A3DR01

Test Report No.: 71368678

Model:	Model No:	for	Implants to be
Application Software	9995	Programmer:	programmed:
(external)		2090	Ensura EN1DR01

Test Report No.: 713006624

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	SW018	2090	RevoMRI (US only)

Test Report No.: 713039234

Model:	Model No:	for Programmer:	Implants to be programmed:
Application Software (external)	9995	2090 29901	Advisa SR MRI SureScan A3SR01 Ensura SR MRI SureScan EN1SR01



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 039709 1199 Rev. 01

Product: Implantable Pacemakers

Test Report No.: 713095776

Model:

Percepta™ Quad CRT-P MRI

SureScan™

Serena™ Quad CRT-P MRI SureScan™

Solara™ Quad CRT-P MRI SureScan™

Percepta™ CRT-P MRI SureScan™

Serena™ CRT-P MRI SureScan™

Solara™ CRT-P MRI SureScan™

Model No:

W4TR04

W4TR05

W4TR06

W1TR04

W1TR05

W1TR06

Variant:

MR Conditional

MR Conditional

MR Conditional

MR Conditional

MR Conditional

MR Conditional

Product: Application Software (external)

Test Report No.: 713095780

Model:

Application
Software
(external)

Model No:

SW040

for

Programmer:

2090

29901

Implants to be programmed:

Percepta™ Quad CRT-P MRI

SureScan™ W4TR04

Serena™ Quad CRT-P MRI

SureScan™ W4TR05

Solara™ Quad CRT-P MRI

SureScan™ W4TR06

Percepta™ CRT-P MRI

SureScan™ W1TR04

Serena™ CRT-P MRI

SureScan™ W1TR05

Solara™ CRT-P MRI

SureScan™ W1TR06



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 039709 1199 Rev. 01

Product: Application Software

Test Report No.: 713095771

Model:	Model No:	for Programmer:	Implants to be programmed:
Azure / Astra Application Software	SW030	2090 29901	Azure™ XT DR MRI SureScan™ W2DR01 Azure™ S DR MRI SureScan™ W3DR01 Azure™ XT SR MRI SureScan™ W2SR01 Azure™ S SR MRI SureScan™ W3SR01 Astra™ XT DR MRI SureScan™ X2DR01 Astra™ S DR MRI SureScan™ X3DR01 Astra™ XT SR MRI SureScan™ X2SR01 Astra™ S SR MRI SureScan™ X3SR01

Product: Implantable Pacemakers

Test Report No.: 713095773

Model:	Model No:	Variant:
Azure™ XT DR MRI SureScan™	W2DR01	MR Conditional
Azure™ S DR MRI SureScan™	W3DR01	MR Conditional
Azure™ XT SR MRI SureScan™	W2SR01	MR Conditional
Azure™ S SR MRI SureScan™	W3SR01	MR Conditional
Astra™ XT DR MRI SureScan™	X2DR01	MR Conditional
Astra™ S DR MRI SureScan™	X3DR01	MR Conditional
Astra™ XT SR MRI SureScan™	X2SR01	MR Conditional
Astra™ S SR MRI SureScan™	X3SR01	MR Conditional



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 039709 1199 Rev. 01

Product: Implantable Pacemakers

Test Report No.: 713105247

Model:

Attesta™ DR MRI SureScan™
Attesta™ L DR MRI SureScan™
Attesta™ S DR MRI SureScan™
Attesta™ SR MRI SureScan™
Sphera™ DR MRI SureScan™
Sphera™ L DR MRI SureScan™
Sphera™ SR MRI SureScan™

Model No:

ATDR01
ATDRL1
ATDRS1
ATSR01
SPDR01
SPDRL1
SPSR01

Variant:

MR Conditional
MR Conditional
MR Conditional
MR Conditional
MR Conditional
MR Conditional
MR Conditional

Product: Application Software (external)

Test Report No.: 713105248

Model:

Application
Software

Model No:

SW043

For Programmer:

2090
29901

Implants to be programmed

Attesta™ DR MRI SureScan™
ATDR01
Attesta™ L DR MRI
SureScan™ ATDRL1
Attesta™ S DR MRI
SureScan™ ATDRS1
Attesta™ SR MRI SureScan™
ATSR01
Sphera™ DR MRI SureScan™
SPDR01
Sphera™ L DR MRI
SureScan™

SPDRL1

Sphera™ SR MRI SureScan™
SPSR01



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 039709 1199 Rev. 01

Product: Application Software (external)

Test Report No.: 713127914

Model:

Model No:

**External Device Manager
System supported:**

CareLink SmartSync Azure
Astra App

D00U003

CareLink SmartSync Device
Manager Patient Connector
24967

Product: Application Software (external)

Test Report No.: 713147242

Model:

Model No:

**External Device Manager
System supported:**

CareLink SmartSync
Percepta Serena Solara App

D00U004

CareLink SmartSync Device
Manager Patient Connector
24967