EC Design Examination Certificate
Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 253 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

Digitally signed by Kojevnikov Dmitrii
Date: 2022.01.28 21:52:41 EET
Reason: MoldSign Signature
Location: Moldova

For Product Family

Heart Therapy Delivery Systems

GMDN Code: 17846

CONCLUSION of EXAMINATION:

Complies with the requirements of Directive 90/385/EEC on Active Implantable Medical Devices Annex II (4)

Registration Number:	**253.100**
Original Approval:	**12 June 2002**
Last Amended on:	**03 March 2021**
Remains valid until:	**26 May 2024**

Signed:

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

Approved model numbers are included in the associated attachment

Not valid without a valid Annex II Section 3 certificate

Note: Changes which could affect conformity with the essential requirements of Directive 90/385/EEC, or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

File Ref	Model Reference	Detail
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-S59	SelectSite™ C304-S59 Deflectable Catheter System
253.100.34 253.100.35	C304-HIS	SelectSite™ C304-HIS Deflectable Catheter system
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-L69	SelectSite™ C304-L69 Deflectable Catheter System
253.100.13 253.100.19 253.100.21 253.100.35	C304-XL74	SelectSite™ C304-XL74 Deflectable Catheter System
253.100.13 253.100.19 253.100.35	6227DEF	Attain® 6227DEF Deflectable Catheter Delivery System
253.100.23 253.100.26 253.100.33 253.100.35	C315S4	C315S4 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S5	C315S5 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S10	C315S10 Delivery Catheter

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.23 253.100.26 253.100.33 253.100.35	C315J	C315J Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315HIS	C315HIS Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H20	C315H20 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H40	C315H40 Delivery Catheter
253.100.27 253.100.33 253.100.35	6250VIS	Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VIC	Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VI-MB2	Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EH	Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EHXL	Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.33 253.100.35	6250VI-MPR	Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MP	Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-AM	Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MB2X	Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-45S	Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-50S	Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-57S	Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MPX	Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-3D	Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.35 253.100.36	6248VI-90	Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90S	Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90L	Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130	Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130L	Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90P	Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90SP	Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130P	Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System

Quality System Approval Certificate
Active Implantable Medical Devices Directive 90/385/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 253 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

For the Product Family

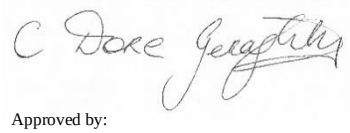
Heart Therapy Delivery Systems

GMDN Code: 17846

On the basis of examination under the requirements of Annex II, Section 3 of Directive 90/385/EEC,
The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product is hereby authorized.

Registration Number:	**253.100**
Original Approval:	**12 June 2002**
Last Amended on:	**03 March 2021**
Remains valid until:	**26 May 2024**

Signed:



Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI.
This certificate must be supported by a valid design examination certificate.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE16

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

For the product / product category

Left Ventricular Lead

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 24 July 2007

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 24 July 2007
Reissued: 1 August 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE16

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Left Ventricular Lead

Issued to:

Medtronic Inc.
710 Medtronic Parkway NE
Minneapolis MN 55432
United States Of America

This certificate covers the following product(s):

Attain Ability™ Model 4196
Attain Ability™ MRI SureScan™ 4196

The product is designed in the facility:

Medtronic, Inc., 8200 Coral Sea Street, Mounds View, MN 55112, USA

EC Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Initial date: 24 July 2007

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE28

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

For the product / product category

Leads for Brady IPGs and their auxiliary components

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 30 April 2018

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 29 September 2023
Issued for the first time: 30 April 2018
Reissued: 29 September 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2007841TE28

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Medtronic Inc.

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

This certificate covers the following product(s):

CapSure Sense MRI™ SureScan® models 4074, 4574
CapSureFix Novus MRI™ SureScan ® model 5076
CapSure Z Novus MRI SureScan TM models 5054, 5554

Initial date: 30 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE29

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

For the product / product category

Leads for Tachy IPGs/ ICDs and their auxiliary components

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 April 2001
Addendum, initially dated 30 April 2018

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 30 March 2024
Issued for the first time: 30 April 2018
Reissued: 30 March 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE29

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Leads for Tachy IPGs/ ICDs and their auxiliary components

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

This certificate covers the following product(s):

Sprint Quattro Secure MRI TM SureScan ™ models 6947, 6947M
Sprint Quattro Secure S MRI™ SureScan™ models 6935, 6935M
Sprint QuattroTM MRI SureScan TM 6946M

Initial date: 30 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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EC CERTIFICATE

Number: 2008481CE01

Full Quality Assurance System

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

Manufacturer:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands

For the product category(ies)

Implantable Pacemaker Systems

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2007317CN, initially dated 15 December 2000
Addendum, initially dated 6 April 2001

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex 2 of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance. For placing on the market of Active implantable medical devices an additional EC design examination certificate according to Annex 2 (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 6 April 2001
Reissued: 1 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2008481CE01

CE MARKING OF CONFORMITY
ACTIVE IMPLANTABLE MEDICAL DEVICES

Implantable Pacemaker Systems

Issued to:

Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands

This certificate covers the following product(s):

Brady Pacemakers

These products are designed/manufactured in the facilities:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design)
Medtronic Europe S.A.R.L., route du Molliau 31, Case Postal., 1131 Tolochenaz, Switzerland (Manufacturing, labeling and final packaging)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Distribution)
Medtronic Singapore Operations Pte. Ltd., 49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056, Singapore (Manufacturing)

Leads for Pacemakers

These products are designed/manufactured in the facilities:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design)
Medtronic Puerto Rico Operations Co. MPRI, Road 149, km 56.3, Villalba PR 00766 USA. (Manufacturing)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Labeling, distribution and final packaging)
Medtronic Rice Creek Pharma Operation, 7000 Central Avenue NE, Minneapolis, Minnesota 55432, USA (manufacturing MCRDs and pharmaceutical analytical testing of MCRDs and leads)

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2008481CE01

CE MARKING OF CONFORMITY
ACTIVE IMPLANTABLE MEDICAL DEVICES

Implantable Pacemaker Systems

Issued to:

Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands

Application software (external)

These products are designed in the facility:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Labeling, distribution and final packaging)

Lead Introducers

These products are designed in the facility:

Medtronic Inc., 8200 Coral Sea Street, Mounds View, MN 5512, USA (Design, manufacturing)
Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands (Distribution)

Initial date: 6 April 2001

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2008481DE24

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

Manufacturer:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands

For the product

Implantable Pacemaker Vitatron G-Series

Documents, that form the basis of this certificate:

Certification Notice 2007317CN, initially dated 15 December 2000
Addendum, initially dated 16 December 2009

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 2 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 2 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 January 2024
Issued for the first time: 16 December 2009
Reissued: 1 January 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

G Adams
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2008481DE24

EC DESIGN-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Implantable Pacemaker Vitatron G-Series

Issued to:

Vitatron Holding B.V.
Endepolsdomein 5
6229 GW Maastricht
The Netherlands

This certificate covers the following product(s):

- Vitatron G70 DR, model G70 A1
- Vitatron G20 SR, model G20 A1
- Vitatron MRI™ SureScan™, G70 DR, model G70A2
- Vitatron MRI™ SureScan™, G20 SR, model G20A2

Initial date: 16 December 2009

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

G Adams
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CERTIFICATE

Number: 2250781

The management system of:

Vitatron Holding B.V.

Endepolsdomein 5
6229 GW Maastricht
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:
Design, Manufacturing and distribution of implantable Pacemaker systems

Certificate expiry date: 1 September 2024
Certificate effective date: 1 September 2021
Certified since: 1 September 2012

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

vitatron	Document Title: *DoC0023*	Document Number: DoC0023
EC DECLARATION OF CONFORMITY	*G-Series A2 models G20A2, G70A2 and Application Software VSF21*	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	22 May 2017
Corrected EC certificate reference from 2008481DE33 to 2008481DE24 for the pulse generators	3.0	24 May 2017
Updated approver role Updated Applicable Standards Date of Issue of EN 45502-1, EN ISO 11607-1, EN 60601-1-6, EN 62304 and Standard Number and Date of Issue of EN 62366-1 ISO 15223-1 was EN 15223-1 Removed Standard ISO 11607-2, does not apply to this device Removed footnotes of EN ISO 14971, EN 60601-1-6, EN 62304 and EN 62366-1 Statement text updated	4.0	17 Aug 2017
Model number: updated Programmer Application Software VSF21 with revision 8.0	5.0	25 Sep 2017
Clarification of VSF21 revision 8.0 for both programmers.	6.0	26 Sep 2017
Updated to reflect MDT30130338 rev 1.0 standards changes from ISO 15223-1:2012 to EN ISO 15223-1:2016	7.0	16-Jul-2018
Updated EN 45502-1 title. Added “Implants for surgery”	8.0	10-Jan-2019
Updated document information to align with current template revision A Updated to match Agile MAP revision numbering convention Added Amendment 1:2019 to EN ISO 11135:2014 Changed EN 60601-1:2006+A1:2013 to EN 60601 1:2006+A12:2014. The change is due to the incorporation of technical corrigendum July 2014 (technical correction of Figure 12).	A	18-Dec-2020
Updated EN ISO 14971 revision from 2012 to 2019 Added standards ISO 14708-1 and ISO 14708-2 Updated EN ISO 10993-1 revision from 2009/AC:2010 to 2020 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019	B	Upon Approval

vitatron

EC Declaration of Conformity

Manufacturer:	Vitatron Holding BV Endepolsdomein 5 6229 GW Maastricht The Netherlands
EC Representative:	N/A
Description of device concerned:	*G-Series Implantable Pulse Generator; Programmer Application Software*
Model number:	*G20A2, G70A2, VSF21*
Variants:	*VSF21 v8.0 (Programmer 2090 and 29901)*
GMDN Code	47265 Dual-chamber pacemaker, rate-responsive 47267 Single-chamber pacemaker, rate-responsive 47206 Cardiac Pulse Generator Software
Classification, rule	AIMD
Conformity Assessment procedure:	*Annex 2.3 with Annex 2.4*
EC Certificate number:	*Implantable Pulse Generator: 2008481DE24* *Programmer application software: 2008481DE20*
EC Quality System Certificate:	*2008481CE01*
Name of Notified Body:	*DEKRA Certification B.V.* *Meander 1051* *6825 MJ Arnhem* *The Netherlands*
Identification Number Notified Body:	*0344*
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Vitatron, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC [1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to change record***

Place: Maastricht

Date: ***Refer to document approval date in the change record***

Name: Cor Mathijsen

Title: EC Management Representative

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] Including amendments issued in the years following

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements following the applicable EC Directive.

The below mentioned Standard(s) apply to all the product(s) mentioned under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be labeled "STERILE"- Part 1: Requirements for terminally sterilized medical devices
EN 1041	2008 + A1:2013	Information Supplied by the Manufacturer with Medical Devices
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 45502-1	2015	Implants for surgery - Active Implantable Medical Devices - Part 1. General requirements for safety, marking and information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active Implantable Medical Devices - Part 1. General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery - Active Implantable Medical Devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN ISO 10993-1	2020	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing within a Risk Management Process
ISO 10993-7	2008 + Amd1:2019	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
EN ISO 11135	2014 + A1:2019	Sterilization of medical devices – Validation and routine control of Ethylene Oxide sterilization
EN ISO 14971	2019	Medical devices-Application of risk management to medical devices
EN ISO 11607-1	2009 + A1:2014	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 5841-3	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
EN 62366-1	2015	Medical devices – Application of usability engineering to medical devices
EN 60601-1-6	2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
EN 60601-1[2]	2006 + A12:2014	Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance
EN 62304	2006 + A1:2015	Medical device software – Software Life-cycle processes

[2] Full Compliance (only clause 14 is applicable)

Medtronic	Document Title: DoC-4196 MRI SureScan	Document Number: BL0030512
EC DECLARATION OF CONFORMITY	Attain Ability™ MRI SureScan™ Lead, Model 4196	

Revision/History description	Revision level	Impl. Date
Initial Release for Attain Ability™ MRI SureScan™ Lead, Model 4196	2.0	18-Jun-2016
Updated to latest revision of DoC template. Updated to reflect new EC Quality System certificate number. New certificate (I2 17 11 39709 01117) replaces certificate I2 12 11 39709 844 and becomes effective November 21, 2017. As such, validity date updated to reflect November 21, 2017. Updated GMDN Code and Description from 35223 (Endocardial pacing lead) to 60190 (Coronary venous pacing lead). Updated compliance level footnotes in Attachment 1.	3.0	17-Oct-2017
Correction to GMDN Code number from 60190 to 60910.	4.0	18-Oct-2017
Updated EN 62366:2008 to EN 62366-1:2015	5.0	11-Apr-2018
Updated to reflect MDT30106734 rev 4.0 Standards Changes: 1. From EN 980:2008 to EN ISO 15223-1:2016 2. From EN 1041:2008 to EN 1041:2008/A1:2013 3. From EN 45502-1:1997 to EN 45502-1:2015	6.0	26-Jun-2018
Updated approver to Jeff Chaput Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018	7.0	03-Dec-2019
Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1:2018 to EN ISO 11135:2014	A	01-Apr-2020
Updated EN ISO 11135:2014+A1:2018 to 11135:2014+A1:2019, updated title	B	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-2 Updated ISO 10993-1:2018 to EN ISO 10993-1:2020	C	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned:	Attain Ability MRI SureScan Lead
Model number:	4196
Variants:	4196-78, 4196-88
GMDN Code and Description	60910, Coronary venous pacing lead
Classification, rule	AIMD
Conformity Assessment Route:	Annex 3 with Annex 5
EC Certificate number:	2007841TE16
EC Quality System Certificate:	I2 17 11 39709 01117
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to document approval date in the change record*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeff Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 45502-1	2015	Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
ISO 14708-1	2014	Implants for surgery - Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices - Part 2-1: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery - Active Implantable Medical Devices - Part 2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers) – Second edition
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2013	Information supplied by the manufacturer with medical devices
EN ISO 11135	2019	Sterilization of health care products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
EN 556-1	2006	Sterilization of medical devices - Requirements for medical devices to be labeled “Sterile”- Part 1: Requirements for terminally sterilized medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Tests for Ethylene Oxide Sterilization Residuals
ISO 5841-3	2013	Cardiac Pacemakers – Pacemaker leads - Connector Assembly (IS-1) for Implantable Pacemakers – Part 1: Safety and Design Requirements
EN 62366-1	2015	Medical devices – Application of usability engineering to medical devices

Medtronic	Document Title: DoC- CapSure Fix Novus MRI SureScan Model 5076	Document Number: BL0026501
EC DECLARATION OF CONFORMITY	CapSureFix® Novus MRI SureScan Model 5076 Active Fixation Pacing Lead	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	15-Mar-2013
Update to add new EC certificate number due to CE Renewal. New certificate (I7 13 09 39709 804) replaces certificate I7 12 02 39709 768 and becomes effective September 30, 2013. As such, validity date updated to reflect September 30, 2013.	3.0	06-Sep-2013
Update EC Cert number to reflect newly released certificate I7 15 07 39709 987	4.0	30-Jul-2015
Update ISO 5841-3 reference to 2013; Update compliance statements 2, 3, & 4.	5.0	30-Jun-2016
Updated quality system certificate number Updated approver to Kiran Kuppuswamy	6.0	06-Apr-2017
Update "I, the undersigned, hereby declare…" with "We, Medtronic, hereby declare under our sole responsibility…" Updated Standards EN ISO 11135:2014 and EN ISO 11607-1:2009+A1:2014 Updated Title for Standards EN 980, EN 1041 and EN ISO 11135	7.0	14-Aug-2017
Updated to reflect full compliance with EN 62366-1:2015 and latest template	8.0	06-Apr-2018
Updated to reflect new EC certificate number. New certificate (2007841TE28) replaces certificate (I7 15 07 39709 987) and becomes effective April 30, 2018. As such, validity date updated to reflect April 30, 2018. Conformity assessment route updated from "Annex 2.3 with Annex 2.4" to "Annex 3 with Annex 5". Update to EC Quality System Certificate to applicable Annex 5 certificate I2 17 11 39709 01117.	9.0	20-Apr-2018
Updated to reflect BL0016630 Rev 19 ERM Standards Changes: 1) From EN 980:2008 To: EN ISO 15223-1:2016 2) From: EN 1041:2008 To: EN 1041:2008/A1:2013 3) From: EN 45502-1:1997 To: EN 45502-1:2015	10.0	13-Jun-2018
Updated from EN ISO 10993-1:2009/AC2010 to ISO 10993-1:2018 Updated approver from Kiran Kuppuswamy to Jeffery Chaput	11.0	26-Nov-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020	12.0	21-Feb-2020
Added Amendment 1:2019 to EN ISO 11135:2014 Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date	A	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-2 Updated ISO 10993-1:2018 to EN ISO 10993-1:2020	B	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned :	CapSureFix® Novus MRI SureScan lead
Model number:	5076
Variants:	Lead Lengths: 35cm, 45cm, 52cm, 58cm, 65cm, 85cm
GMDN Code and Description	35223, Endocardial pacing lead
Classification, rule	AIMD
Conformity Assessment Route:	Annex 3 with Annex 5
EC Certificate number:	2007841TE28
EC Quality System Certificate:	I2 17 11 39709 01117
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***30-Apr-2018*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeffery Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2006	Sterilization of medical devices - Requirements for medical devices to be labeled “Sterile”- Part 1: Requirements for terminally sterilized medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2008 + A1:2013	Information supplied by the manufacturer of medical devices
ISO 5841-3	2013	Cardiac Pacemakers – Pacemaker leads - Connector Assembly (IS-1) for Implantable Pacemakers – Part 1: Safety and Design Requirements
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Tests for Ethylene Oxide Sterilization Residuals
EN ISO 11135	2014 +A1:2019	Sterilization of health care products – Ethylene Oxide – Requirements for development, Validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN 45502-1	2015	Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices - Part 2-1: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery – Active Implantable Medical Devices – Part 2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers) – Second edition
EN 62366-1	2015	Medical Devices – Part 1: Applications of Usability Engineering to Medical Devices

Medtronic	Document Title: DoC-6215	Document Number: BL0003803
EC DECLARATION OF CONFORMITY	Model 6215 Attain Venogram Balloon Catheter	

Revision/History description	Revision level	Impl. Date
Attain Venogram Balloon Catheter, Model 6215	-	29-AUG-2001
Update to implement new EC Rep Address, editorial changes, new CE mark certificate	A	25-MAR-2004
Update to align CE mark following update of CE mark from OEM, editorial changes	4.0	13-FEB-2008
Updated to support MD Directive 93/42/EEC: Amendment 2007 and New Template. Corrected Issue Date.	5.0	27-APR-2010
Updated Standards, New DoC Template Rev 7.0	6.0	19-JUN-2012
Updated to add new design certificate number due to CE Renewal; update to latest revision of DoC template 8.0	7.0	23-JAN-2013
Updated to add new quality system certificate G1 13 02 39709 857 which replaces G1 12 02 39709 781	8.0	26 June 2013
Added EN ISO 14971:2012	9.0	25 July 2013
Updated to add new Quality System Certificate number	10.0	27 Mar 2015
Updated approver to Stacey Pivovar Updated referenced Standards for EN ISO 11135, EN ISO 10555, EN ISO 11607, Added EN 62366:2008 to referenced standards Updated titles for EN ISO 11135, EN ISO 10555 Updated Compliance for EN ISO 10993-1: 2009/AC:2010 and EN ISO 14971: 2012	11.0	17 Oct 2016
Update revision of standards EN ISO 11135, EN ISO 10555 Updated approver to Kiran Kuppuswamy	12.0	06-Apr-2017
Updated to latest revision of DoC template. Updated to reflect new EC certificate number. New certificate (G7 17 08 39709 01118) replaces certificate (G7 13 01 39709 856) and becomes effective February 3, 2018. As such, validity date updated to reflect February 3, 2018.	13.0	11-Dec-2017
Corrected Directive listing to 93/42/EEC.	14.0	22-Feb-2018
Updated referenced Standards for ISO 11135:2014, and EN 62366-1:2015	15.0	08-Mar-2018
Updated footnote ([4] Full compliance only for the design changes made to released product) removed to reflect Full Compliance to standard EN 62366-1:2015.	16.0	15-Mar-2018
Updated to reflect new EC Quality System certificate number. New certificate (G1 18 02 39709 01144) replaces certificate (G1 15 02 39709 975).	17.0	26-Apr-2018
Updated to reflect BL0016436 Rev 15.0 standards changes: • From EN 980:2008 to EN ISO 15223 -1:2016 • From EN 1041:2008 to EN 1041:2008/A1:2013	18.0	15-Jan-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Updated EC Quality System Certificate number	19.0	21-Oct-2019
Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1:2018 to EN ISO 11135:2014	AA	01-Apr-2020
Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019	AB	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-2	AC	Upon Approval

Updated ISO 10993-1:2018 to EN ISO 10993-1:2020		

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned :	Attain Venogram Balloon Catheter
Model number:	6215
Variants:	Not applicable
GMDN Code and Description	10688, Angiographic catheter, single-use
Classification, rule	Class III, Rule 6
Conformity Assessment Route:	Annex 2.3 with Annex 2.4
EC Certificate number:	G7 17 08 39709 01118
EC Quality System Certificate:	G1 039709 1144
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 93/42/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to document approval date in the change record***

Place: Minneapolis

Date: ***Refer to document approval date in the change record***

Name: Jeff Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 1041	2008 + A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 10555-1	2013 Cor 2014	Sterile, Single-Use Intravascular Catheters - Part 1: General Requirements
EN ISO 10993-1	2020	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing within a Risk Management Process
ISO 10993-7	2008 + Amd1:2019	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
ISO 11135	2014 +A1:2019	Sterilization of health-care products - Ethylene Oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
ISO 14708-2	2019	Implants for surgery - Active implantable medical devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) – Second edition

Medtronic	Document Title: DoC- Sprint Quattro Secure S MRI SureScan Model 6935M	Document Number: BL0028236
EC DECLARATION OF CONFORMITY	Sprint Quattro Secure S MRI™ SureScan™ Model 6935M tripolar, active fixation lead for pacing, sensing, cardioversion, and defibrillation	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	31 March 2014
Update to add new EC certificate number. New certificate (I7 14 07 39709 938) replaces certificate I7 14 03 39709 932.	3.0	1 July 2015
Standard revision review as part of the 3T MRI labelling expansion and aligns with version 8 of ER Matrix BL0024033 and new CE certificate I7 16 01 39709 01027	4.0	25-Feb-2016
Updated quality system certificate number Updated approver to Kiran Kuppuswamy	5.0	07-Apr-2017
Correction to listing for EN 62366-1. Updated to reflect new EC certificate number. New certificate (2007841TE29) replaces certificate (I7 16 01 39709 01027) and becomes effective April 30, 2018. As such, validity date updated to reflect April 30, 2018. Conformity assessment route updated from “Annex 2.3 with Annex 2.4” to “Annex 3 with Annex 5”. Update to EC Quality System Certificate to applicable Annex 5 certificate I2 17 11 39709 01117.	6.0	18-Apr-2018
Updated to reflect BL0024732 Rev 13 ERM Standards Changes: 1) From EN 980:2008 To: EN ISO 15223-1:2016 2) From: EN 1041:2008 To: EN 1041:2008/A1:2013 3) From: EN 45502-1:1997 To: EN 45502-1:2015	7.0	14-Jun-2018
Updated Standards EN ISO 11607 and EN ISO 11135	8.0	15-Jan-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2019	9.0	04-Dec-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020	10.0	21-Feb-2020
Added Amendment 1:2019 to EN ISO 11135:2014, updated title Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date	A	12-Oct-2020
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Added standards ISO 14708-1 and ISO 14708-6 Updated ISO 10993-1:2018 to EN ISO 10993-1:2020	B	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned : Model number: Variants:	Sprint Quattro Secure S MRI™ SureScan™ 6935M Lead Lengths: 55cm, 62cm
GMDN Code and Description	35853, Endocardial defibrillation lead
Classification, rule	AIMD
Conformity Assessment Route:	Annex 3 with Annex 5
EC Certificate number:	2007841TE29
EC Quality System Certificate:	I2 17 11 39709 01117
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***30-Apr-2018*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeff Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2001/AC: 2006	Sterilization of medical devices – Requirements for medical devices to be designated “Sterile” – Part 1: requirements for terminally sterilized medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1	2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
EN ISO 11135	2014 + A1:2019	Sterilization of healthcare products —Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
ISO 27186	2010	Active implantable medical devices – Four pole connector system for implantable cardiac rhythm management devices – Dimensional and test Requirements
EN 45502-1	2015	Implants for surgery - Active implantable medical devices – Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices – Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer
EN 45502-2-2	2008/AC: 2009	Active implantable medical devices –Part 2- 2: Particular requirements for AIMDs Intended to Treat Tachyarrhythmia (includes implantable defibrillators)
ISO 14708-6	2019	Implants for surgery - Active implantable medical devices –Part 6: Particular requirements for AIMDs Intended to Treat Tachyarrhythmia (includes implantable defibrillators) – Second edition
EN 62366-1	2015	Medical Devices – Part 1: Applications of Usability Engineering to Medical Devices

Medtronic	Document Title: **EC DoC- Percepta/Serena/Solara Family of Devices**	Document Number: **DSN024248** DHF Project Name: **CRT-P Quad** Deliverable: **Declaration of Conformity**
EC DECLARATION OF CONFORMITY	**Percepta/Serena/Solara CRT-P MRI SureScan devices**	

Revision/History description	Revision level	Impl. Date
Initial Release for Percepta™/Percepta™ Quad, Serena™/Serena™ Quad, and Solara™/Solara™ Quad CRT-P MRI SureScan™ devices (Percepta/Serena/Solara family of devices) and Application Software (external) Model SW040	2.0	13-Feb-2017
Updated to template Rev AA Added "DHF Project Name: CRT-P Quad" to Header Updated EC Quality System certificate I1 17 11 39709 01115 (effective November 21, 2017) replaces I1 12 11 39709 842 Updated 'Validity DoC from date: Refer to cover page' to 21-November-2017 in line with new certificate effective date Updated approver name and title Updated Standard Titles to EN 1041 and EN ISO 10993-1 Updated to correct prefix and title of EN ISO 11135 Updated to correct revision of EN ISO 11607-1 Updated to correct omitted Part Number in EN 62366-1 to agree with revision year Updated Standards EN 60601-1, EN 60601-1-6, EN 62304	3.0	20-Oct-2017
Updated to reflect new EC Quality System certificate number. New certificate (I1 18 03 39709 01185) replaces certificate I1 13 02 39709 855 and becomes effective May 2, 2018. As such, validity date updated to reflect May 2, 2018.	4.0	20-Apr-2018
Updated to reflect new EC certificate number. New certificate (I7 18 04 39709 01191) replaces certificate I7 15 07 39709 987 and is effective as of April 30, 2018.	5.0	03-May-2018
Updated to reflect new EC Certificate number. New certificate (I7 039709 1199) replaces certificate I7 18 04 39709 01191 and becomes effective September 30, 2018. As such, validity date updated to reflect September 30, 2018.	6.0	09-Sep-2018
Updated to add Device App for SmartSync and updating Standards	7.0	18-Jan-2019
-Correct standard "ISO 15223-1" to "EN ISO 15223-1".Update "EN 60601-1" standard date of issue to "2006/A12:2014". -Application D00U004 is approved on June 17, 2019, updated to reflect effective date of new certificate. -Updated approver name and title on certificate	A	30-May-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Changed "cover page" to "change record" to match Agile approval process	B	02-Dec-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1 :2018 to EN ISO 11135:2014	C	01-Apr-2020
Updated to reflect compliance to EN 82304-1:2017 NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.	D	13-Apr-2020
Updated Quality System Certificate Number. New certificate (I1 039709 1115) replaces existing certificate (I1 17 11 39709 01115) and becomes effective 01 June 2020.	E	02-Jun-2020
Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019	F	12-Oct-2020
Updated EC Quality System Certificate Number. New certificate (I1 039709 1185) replaces existing certificate and becomes effective 23 April 2021.	G	18-May-2021
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Updated EN ISO 10993-1 revision from 2018 to 2020	H	Upon Approval

Added standards ISO 14708-1, ISO 14708-2 Clause 6, and ISO 14708-6		

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned :	Percepta™, Serena™, Solara™ implantable cardiac pacemakers with cardiac resynchronization therapy (CRT-P) and SureScan Technology and Programmer Application Software (External)
Model number:	See Attachment 2
Variants:	None
GMDN Code and Description	47263, Cardiac resynchronization therapy implantable pacemaker 47206, Cardiac pulse generator software
Classification, rule	AIMD
Conformity Assessment Route:	Annex 2.3 combined with 2.4
EC Certificate number:	I7 039709 1199 (for device models and SW040 & D00U004, external application software)
EC Quality System Certificate:	I1 039709 1185 (for device models) I1 039709 1115 (for application software)
Name & Address of Notified Body:	TUV SÜD PS GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date:***Refer to change record*** Place: Minneapolis Date: ***Refer to change record***

Name: Jeffrey Chaput
Title: Sr. Software Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the Percepta/Serena/Solara model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements Second Edition
EN 1041	2008 + Amd1: 2013	Information supplied by the manufacturer of medical devices
ISO 5841-3	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices - Part 1: Evaluation And Testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical devices - Part 7: Ethylene Oxide sterilization residuals
EN ISO 11135	2014 + A1:2019	Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
EN 45502-1	2015	Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 45502-2-1 Clause 6	2003	Implants for surgery - Active implantable medical devices -- Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
ISO 14708-2 Clause 6	2019	Implants for surgery - Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN 45502-2-2	2008/AC: 2009	Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
ISO 14708-6	2019	Implants for surgery - Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) – Second edition
EN 62304	2006 + A1:2015	Medical device software. Software life-cycle processes
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 82304-1: 2017	2017	Health software – Part 1: General requirements for product safety NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.

The below mentioned Standard(s) apply to the external software (SW040 & D00U004) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements Second Edition
EN 1041	2008 + Amd1:2013	Information supplied by the manufacturer of medical devices
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
EN 45502-1	2015	Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 60601-1 Clause 14	2006 + A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-6	2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
EN 62304	2006 + A1:2015	Medical device software. Software life-cycle processes
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 82304-1: 2017	2017	Health software – Part 1: General requirements for product safety NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.

Attachment 2: Model Listing

The following models are included under the scope of this DoC:

Model Name	Model Number(s)	Variant(s)
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	Not applicable
Percepta™ CRT-P MRI SureScan™	W1TR04	Not applicable
Serena™ Quad CRT-P MRI SureScan™	W4TR05	Not applicable
Serena™ CRT-P MRI SureScan™	W1TR05	Not applicable
Solara™ Quad CRT-P MRI SureScan™	W4TR06	Not applicable
Solara™ CRT-P MRI SureScan™	W1TR06	Not applicable
External application software (2090, Encore) for Percepta/Serena/Solara Family of Devices	SW040	Not applicable
External application software (SmartSync) for Percepta/Serena/Solara Family of Devices	D00U004	Not applicable

Medtronic	Document Title: DoC-Primo MRI and Mirro MRI ICDs and SW033 DHF Project Name: HP MRI	Document Number: DSN026518 Deliverable: Declaration of Conformity
EC DECLARATION OF CONFORMITY	**Primo MRI™ SureScan™ and Mirro MRI™ SureScan™ Implantable Cardioverter Defibrillators and Application Software SW033**	

Revision/History description	Revision level	Impl. Date
Initial Release	2.0	15-Nov-2017
Updated to reflect new EC Quality System certificate number. New certificate (I1 18 03 39709 01185) replaces certificate I1 13 02 39709 855 and becomes effective May 2, 2018. As such, validity date updated to reflect May 2, 2018.	3.0	20-Apr-2018
Updated to reflect new EC certificate number. New certificate (I7 18 04 39709 01192) replaces certificate I7 16 01 39709 01027 and is effective as of April 30, 2018.	4.0	03-May-2018
Updated to reflect DSN013032 Rev 15 ERM Standards Changes: 1) From: EN 980:2008 To: EN ISO 15223-1:2016 2) From: EN 1041:2008 To: EN 1041:2008/A1:2013	5.0	11-Jul-2018
Updated DoC DSN026518 to reflect new EC certificate number for application software which becomes valid March 31, 2019. Validity date updated to reflect March 31, 2019. Administrative updates to date and signature verbiage to refer to electronic change record. Administrative updates to document attributes in Agile MAP.	A	31-Mar-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Corrected format of applicable standards in attachment 1	B	06-Dec-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1 :2018 to EN ISO 11135:2014	C	01-April-2020
Updated Quality System Certificate Number. New certificate (I1 039709 1115) replaces existing certificate (I1 17 11 39709 01115) and becomes effective 01 June 2020.	D	02-Jun-2020
Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019 Changed EN 60601-1:2006+A1:2013 to EN 60601-1:2006+A12:2014. The change is due to the incorporation of technical corrigendum July 2014 (technical correction of Figure 12).	E	12-Oct-2020
Updated EC Quality System Certificate Number. New certificate (I1 039709 1185) replaces existing certificate and becomes effective 23 April 2021.	F	18-May-2021
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Updated EN ISO 10993-1 revision from 2018 to 2020 Added standards ISO 14708-1:2014, ISO 14708-2:2019 Clause 6, and ISO 14708-6:2019	G	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned:	Primo MRI™ and Mirro MRI™ SureScan™ Implantable Cardioverter-Defibrillator (ICD) Devices and Application Software (External)
Model number:	See Attachment 2
Variants:	Not Applicable
GMDN Code and Description	37265, Dual-chamber implantable defibrillator and 35852, Single Chamber Implantable Defibrillator **47206, Cardiac pulse generator software**
Classification, rule	AIMD
Conformity Assessment Route:	Annex 2.3 with 2.4
EC Certificate number:	I7 17 10 39709 01141 (for devices) I7 039709 1192 (for application software)
EC Quality System Certificate:	I1 039709 1185 (for devices) I1 039709 1115 (for application software)
Name & Address of Notified Body:	TUV SUD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to document approval date in the change record***

Place: Minneapolis

Date: ***Refer to document approval date in the change record***

Name: Jeffrey Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 556-1	2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be labeled "Sterile" – Part 1: requirements for terminally sterilized medical devices
EN ISO 15223-1	2016	Symbols for use in the labelling of medical devices
EN 1041	2008 + A1:2013	Information supplied by the manufacturer of medical devices
ISO 5841-3[2]	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Tests for Ethylene Oxide Sterilization Residuals
EN ISO 11135	2014 + A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11318	2002	Cardiac Defibrillators – Connector assembly DF-1 for implantable defibrillators - Dimensions and test requirements
ISO 11607-1	2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
ISO 27186	2010	Active implantable medical devices -- Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements
EN 45502-1	2015	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1[3] Clause 6	2003	Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
ISO 14708-2 Clause 6	2019	Implants for surgery - Active implantable medical devices - Part 2: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN 45502-2-2	2008/AC:2009	Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
ISO 14708-6	2019	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) – Second edition
EN 60601-1[4] Clause 14	2006 + A12:2014	Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance

[2] *EN 50077:1993 Low-Profile connector for implantable pacemakers is equivalent to ISO 5841-3*
[3] *Full Compliance (only clause 6 applies for ICD devices)*
[4] *Full Compliance (only clause 14 is applicable)*

EN 60601-1-6	2010 + A1:2015	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304	2015	Medical device software. Software life-cycle processes
EN 62366-1	2006 + A1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

Attachment 2: Model Listing

The following models are included under the scope of this DoC:

Model Name	Model Number(s)	Variant(s)
Primo MRI™ VR SureScan™	DVMD3D1, DVMD3D4	N/A
Mirro MRI™ VR SureScan™	DVME3D1, DVME3D4	N/A
Primo MRI™ DR SureScan™	DDMD3D1, DDMD3D4	N/A
Mirro MRI™ DR SureScan™	DDME3D1, DDME3D4	N/A
Model SW033 Programmer Software Application	SW033	N/A

EC CERTIFICATE

Number: 2181711CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Bioptimal International PTE. LTD.

36 Jalan Tukang
619266 Singapore
Singapore

For the product category(ies)

Critical Care Products used in intensive care units, critical care units, percutaneous interventional environments, operating theatres and nursing departments

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:
Certification Notice 2181711CN, initially dated 15 July 2015
Addendum, initially dated 11 December 2015

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 15 July 2015
Reissued and Revised: 30 March 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2181711CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Critical Care Products used in intensive care units, critical care units, percutaneous interventional environments, operating theatres and nursing departments

Issued to:

Bioptimal International PTE. LTD.
36 Jalan Tukang
619266 Singapore
Singapore

This certificate covers the following product(s):

- Angiographic Kit – Class IIa
- Pressure Monitoring Systems and Kits – Class IIa
  - Accutrans
  - Catrans
  - Biotrans
- Embolectomy Catheter – Class IIa
- Central Venous Catheter and Catheterization Kit – Class III
- Bipolar Pacing Catheter – Class III
- Thermodilution Catheter and Kits – Class III
- Pulmonary Artery Monitoring Catheter and Kits – Class III
- Vascular Introducer Kit – Class IIa

Initial date: 11 December 2015

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 634279**

Issued To: **Osypka AG**
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

In respect of:

VACS Percutaneous Transluminal Valvuloplasty Catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Intended purpose per IFU: This product is recommended for percutaneous transluminal valvuloplasty. Possible indications: Outflow tract - stenosis of the right and left ventricle, Pulmonary valve stenosis, Aortic valve stenosis, Peripheral pulmonary artery stenosis, Aortic isthmus stenosis, Aortic valve pre-dilation prior to TAVI procedures.

Classification: Class III

Catalogue Number	Device Name	Model, Type
YA0010	VACS II	4.0 x 20
YA0011	VACS II	5.0 x 20
YA0012	VACS II	6.0 x 20
YA0013	VACS II	7.0 x 20
YA0014	VACS II	7.0 x 30
YA0015	VACS II	8.0 x 20
YA0016	VACS II	8.0 x 30
YA0018	VACS II	9.0 x 20
YA0019	VACS II	9.0 x 30
YA0020	VACS II	10.0 x 20
YA0021	VACS II	10.0 x 30
YA0022	VACS II	10.0 x 40
YA0023	VACS II	12.0 x 20
YA0024	VACS II	12.0 x 30
YA0025	VACS II	12.0 x 40

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Catalogue Number	Device Name	Model, Type
YA0026	VACS II	12.0 x 60
YA0027	VACS II	14.0 x 30
YA0028	VACS II	14.0 x 40
YA0029	VACS II	14.0 x 50
YA0030	VACS II	14.0 x 60
YA0031	VACS II	15.0 x 30
YA0032	VACS II	15.0 x 40
YA0033	VACS II	15.0 x 50
YA0034	VACS II	15.0 x 60
YA0035	VACS II	16.0 x 30
YA0036	VACS II	16.0 x 40
YA0037	VACS II	16.0 x 50
YA0038	VACS II	16.0 x 60
YA0039	VACS II	17.0 x 30
YA0040	VACS II	17.0 x 40
YA0041	VACS II	17.0 x 50
YA0042	VACS II	17.0 x 60
YA0043	VACS II	18.0 x 30

Catalogue Number	Device Name	Model, Type
YA0044	VACS II	18.0 x 40
YA0045	VACS II	18.0 x 50
YA0046	VACS II	18.0 x 60
YA0047	VACS II	20.0 x 30
YA0048	VACS II	20.0 x 40
YA0049	VACS II	20.0 x 50
YA0050	VACS II	20.0 x 60
YA0051	VACS II	22.0 x 30
YA0052	VACS II	22.0 x 40
YA0053	VACS II	22.0 x 50
YA0054	VACS II	22.0 x 60
YA0055	VACS II	24.0 x 30
YA0056	VACS II	24.0 x 40
YA0057	VACS II	24.0 x 60
YA0058	VACS II	26.0 x 30
YA0059	VACS II	26.0 x 40
YA0060	VACS II	26.0 x 50
YA0061	VACS II	26.0 x 60

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Catalogue Number	Device Name	Model, Type
YA0062	VACS II	28.0 x 30
YA0063	VACS II	28.0 x 40
YA0064	VACS II	28.0 x 50
YA0065	VACS II	28.0 x 60
YA0066	VACS II	30.0 x 30
YA0067	VACS II	30.0 x 40
YA0068	VACS II	30.0 x 50
YA0069	VACS II	30.0 x 60
YA30520	VACS III	5.0 x 20
YA30620	VACS III	6.0 x 20
YA30720	VACS III	7.0 x 20
YA30820	VACS III	8.0 x 20
YA30830	VACS III	8.0 x 30
YA30920	VACS III	9.0 x 20
YA30930	VACS III	9.0 x 30
YA31020	VACS III	10.0 x 20
YA31030	VACS III	10.0 x 30
YA31040	VACS III	10.0 x 40

Catalogue Number	Device Name	Model, Type
YA31220	VACS III	12.0 x 20
YA31230	VACS III	12.0 x 30
YA31240	VACS III	12.0 x 40
YA31260	VACS III	12.0 x 60
YA31430	VACS III	14.0 x 30
YA31440	VACS III	14.0 x 40
YA31460	VACS III	14.0 x 60
YA31530	VACS III	15.0 x 30
YA31540	VACS III	15.0 x 40
YA31630	VACS III	16.0 x 30
YA31640	VACS III	16.0 x 40
YA31660	VACS III	16.0 x 60
YA31830	VACS III	18.0 x 30
YA31840	VACS III	18.0 x 40
YA31860	VACS III	18.0 x 60
YA32040	VACS III	20.0 x 40
YA32050	VACS III	20.0 x 50
YA32060	VACS III	20.0 x 60

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Catalogue Number	Device Name	Model, Type
YA32240	VACS III	22.0 x 40
YA32250	VACS III	22.0 x 50
YA32260	VACS III	22.0 x 60
YA32340	VACS III	23.0 x 40
YA32350	VACS III	23.0 x 50
YA32360	VACS III	23.0 x 60
YA32440	VACS III	24.0 x 40
YA32460	VACS III	24.0 x 60
YA32540	VACS III	25.0 x 40
YA32550	VACS III	25.0 x 50
YA32560	VACS III	25.0 x 60
YA32640	VACS III	26.0 x 40
YA32660	VACS III	26.0 x 60
YA32840	VACS III	28.0 x 40
YA32860	VACS III	28.0 x 60
YA33040	VACS III	30.0 x 40
YA33060	VACS III	30.0 x 60

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 634279

Issued To:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Certificate History

Date	Reference Number	Action
22 July 2016	10161066	First Issue – Transfer from another Notified Body.
29 January 2019	9630089	Changes to the laser welding process and balloon folding process. IFU update (change of retraction rotation direction).
27 February 2019	8586436	Traceable to NB 0086.
Current	9758242	Certificate Renewal. Addition of subcontractor "Osypka s.r.o, Odry – Czech Republic" for the activity of manufacturing. Update of supplementary information page to include intended purpose per IFU and device classification as per current BSI template. Reformatting of device models table.

First Issued: **2016-07-22** Date: **2020-06-04** Expiry Date: **2024-05-26**

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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1144 Rev. 02

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies): **External pacemakers, diagnostic and ablation catheter, transseptal needles**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159141

Valid from: 2020-03-03
Valid until: 2024-05-26

Date, 2020-02-28

Christoph Dicks
Head of Certification/Notified Body

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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 08 39709 01118

Manufacturer:

Medtronic Inc.
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative:

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

Product:

Catheters for single use
Cardiac Balloon Catheters

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 MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713097898

Valid from: 2018-02-03
Valid until: 2023-02-02

Date, 2017-12-06

Stefan Preiß

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Product Service

EC Certificate
EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 08 39709 01118

Model(s): **Attain Venogram Balloon Catheter 6215**

Parameters: ./.

Facility(ies): Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

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Declaration of Conformity

Legal Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Authorized Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Design Facility:	Medtronic Inc. 8200 Coral Sea Street Mounds View, MN 55112 USA
Manufacturing Facility:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Product Family/ies:	Heart Therapy Delivery Systems
Products:	See Attachment
Classification:	Directive 90/385/EEC (AIMD)

Notified Body	NSAI (0050)
EC Quality Certificate	253.100 issued on 12 June 2002
EC Design Certificate	253.100

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 90/385/EEC (AIMD), including amendments issued, which apply to them, as transposed into

the national laws of the EU member states, as well as the following applicable standards and guidance documents:

- Reference standards listed on the appropriate ER Checklist for each product family.

This declaration is supported by the AIMD, Annex II.3 Approval as well as the EC Design Examination Certificate listed above.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Medtronic Inc. Date: 03-MAR-2021

Name: Ryan Calabrese

Title Sr. Regulatory Affairs Director Signature

Products: Heart Therapy Delivery Systems

Model Name	Model No.	Approval Date	Approval Number
SelectSite™ C304-S59 Deflectable catheter system	C304-S59	Mar. 24, 2004 October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/03 253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-L69 Deflectable catheter system	C304-L69		
SelectSite™ C304-XL74 Deflectable catheter system	C304-XL74	October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-HIS Deflectable catheter system	C304-HIS	July 29, 2020 March 3, 2021	253.100/34 253.100/35
Attain® 6227DEF Deflectable Catheter Delivery System	6227DEF	October 11, 2006 October 3, 2008 March 3, 2021	253.100/13 253.100/19 253.100/35

Model Name	Model No.	Approval Date	Approval Number
C315S4 Delivery Catheter	C315S4	October 28, 2010 June 28, 2012 January 21, 2020 March 3, 2021	253.100/23 253.100/26 253.100/33 253.100/35
C315S5 Delivery Catheter	C315S5		
C315S10 Delivery Catheter	C315S10		
C315J Delivery Catheter	C315J		
C315HIS Delivery Catheter	C315HIS		
C315H20 Delivery Catheter	C315H20		
C315H40 Delivery Catheter	C315H40		

Model Name	Model No.	Approval Date	Approval Number
Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System	6250VIC	March 06, 2013 January 21, 2020 March 3, 2021	253.100/27 253.100/33 253.100/35
Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System	6250VIS		
Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery	6250VI-45S		
Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery	6250VI-50S		
Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery	6250VI-57S		
Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left-Heart Delivery	6250VI-AM		
Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery	6250VI-EH		
Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery	6250VI-EHXL		
Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery	6250VI-MB2		
Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery	6250VI-MB2X		
Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery	6250VI-MP		
Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery	6250VI-MPR		
Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery	6250VI-MPX		
Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery	6250VI-3D		

Model Name	Model No.	Approval Date	Approval Number
Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System	6248VI-90	March 06, 2013 May 27, 2020 March 3, 2021	253.100/27 253.100/36 253.100/35
Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System	6248VI-90S		
Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System	6248VI-90L		
Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System	6248VI-130		
Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System	6248VI-130L		
Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System	6248VI-90P		
Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System	6248VI-90SP		
Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System	6248VI-130P		

Revision History

Revision	Date	Description of Change
1A	September 2010	Updated to include amendment number for the modified Attain Select II 6248DEL (Amendment # 253.100/22)
1B	November 2010	Updated to include the amendment number for the modified SelectSite™ C304 Deflectable Catheter System (Amendment # 253.100/21) and to add reference to the C315 Delivery Catheter product family (Amendment # 253.100/23)
1C	June 2011	Transpose into new template FTDOP116978-13 rev 1B. Update issue date of the EC Certificates. Remove Attain 6226DEF which is no longer manufactured. Other minor typographical updates.
1D	June 2011	Correct page numbering in the footer. Correction to a Typographical error only. No impact on the DoC content.
1E	November 2011	Updated to include amendment number for the modified Attain 6216A/6218A product family. Minor documentation updates also completed to align model names and formatting with the Design Examination Cert.
1F	July 2012	Updated to include amendment number for implementation of additional sterilisation site (Sterigenics) for the C315 Delivery Catheters and to update title of signatory
1G	March 2013	Updated to add the Attain Command + SureValve and Attain Select II + SureValve product family model names and numbers and their approval details (approval date/approval number).
1H	June 2014	Updated to remove Attain Prevail as product is no longer manufactured or in distribution. Updated also to list the specific model numbers for the Attain Select™ II delivery catheter systems and to reflect re-certification approval by NSAI
1J	November 2015	Updated to include amendment number for implementation of sterilsation cycle 7 for Attain Select™ II delivery catheter systems
1K	May 2017	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate
1L	July 2017	Updated to reflect re-certification approval by NSAI. Revision number corrected in footer.
AA	May 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI. Update to current template revision FTDOP116978-13 Rev. AB.
AB	August 2020	Update to include amendment number for tip material change for C315 Delivery Catheter, Attain Command + SureValve and Attain Select II + SureValve product familes (file 253.100.33, 253.100.36). Add C304-HIS product family model name, number and approval dates as per file 253.100.34.
AC	August 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI.
AD	November 2020	Update to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35

		under review with NSAI.
AE	March 2021	Updated to reflect re-certification approval by NSAI (File 253.100.35). Removed Attain Command, Attain Select II, Attain 6216A/6218A models as product is no longer manufactured or in distribution, and has been removed from the EC Design Examination Certificate as per file 253.100.35. Updated to current template.

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Product Service

EC Certificate

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

No. I1 039709 1185 Rev. 01

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product:

Brady IPGs
Tachy IPGs/ICDs
Implantable Monitoring and Recording Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:I1 039709 1185 Rev. 01

Report no.: 713194270

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-03-31

Christoph Dicks
Head of Certification/Notified Body

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Product Service

EC Certificate

Production Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5
(Other devices than custom made or intended for clinical investigation)

No. I2 17 11 39709 01117

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

Product:
Implantable Leads for AIMDs
Accessories for Implantable Leads for AIMDs

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 5. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 3 certificate is mandatory. See also notes overleaf.

Report No.: 713108566

Valid from: 2017-11-21
Valid until: 2022-11-20

Date, 2017-09-13

Stefan Preiß

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Product Service

EC Certificate
Production Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5
(Other devices than custom made or intended for clinical investigation)

No. I2 17 11 39709 01117

Facility(ies):

Medtronic Puerto Rico Operations Co., Villalba
Rd. 149, Km. 56.3, Call Box 6001, Villalba, PR 00766, USA

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore
486056, SINGAPORE

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

Medtronic Bakken Research Center B.V.
Endepolsdomein 5, 6229 GW Maastricht, THE NETHERLANDS

Design Facility(ies):

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

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Product Service

EC Certificate

Production Quality Assurance System
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5
(Other devices than custom made or intended for clinical investigation)

No. I2 039709 1117 Rev. 01

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product:

Implantable Leads for AIMDs
Accessories for Implantable Leads for AIMDs

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 5. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 3 certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:I2 039709 1117 Rev. 01

Report no.: 713194256

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-03-31

Christoph Dicks
Head of Certification/Notified Body

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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 17 10 39709 01141

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

EC-Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
THE NETHERLANDS

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.: 713114729

Valid from: 2017-11-10
Valid until: 2022-11-09

Date, 2017-11-10

Stefan Preiß

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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 17 10 39709 01141

Model(s): **see attachment**

Parameters: ./.

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 Molliau 31, Case Postale, 1131 Tolochenaz, SWITZERLAND

Design Facility(ies):

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

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Product Service

Attachment for Certificate no I7 17 10 39709 01141
dated 2017-11-10

Product: **Implantable Cardioverter / Defibrillator Systems**

Test Report No.: 713114729

Model:	**Model No:**	**Variant:**
Primo MRI™ DR SureScan™	DDMD3D4	MR Conditional
Primo MRI™ DR SureScan™	DDMD3D1	MR Conditional
Primo MRI™ VR SureScan™	DVMD3D4	MR Conditional
Primo MRI™ VR SureScan™	DVMD3D1	MR Conditional
Mirro MRI™ DR SureScan™	DDME3D4	MR Conditional
Mirro MRI™ DR SureScan™	DDME3D1	MR Conditional
Mirro MRI™ VR SureScan™	DVME3D4	MR Conditional
Mirro MRI™ VR SureScan™	DVME3D1	MR Conditional

Munich, MHS-CRT, 2017-11-10

Stefan Preiß
Certification Medical Technology

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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 0948 Rev. 01

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product: **Impl. Monitoring and Recording 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.: 713173221

Valid from: 2020-06-08
Valid until: 2024-05-26

Date, 2020-05-19

Christoph Dicks
Head of Certification/Notified Body

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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 039709 0948 Rev. 01

Model(s): **see below**

Product: **Impl. Monitoring and Recording Systems**

Test Report No.: 71368814

Model:	**Model no.:**	**Variant:**
Reveal XT	9529	MR conditional
Reveal XT Patient Assistant	9539	-

Test Report No.: 713056429

Model:	**Model no.:**	**Variant:**
Patient Assistant	PA96000	-

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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. 00

Manufacturer: **Medtronic Inc.**
710 Medtronic Parkway N.E.
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: 2018-09-30
Valid until: 2023-09-29

Date, 2018-09-19

Stefan Preiß

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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 039709 1199 Rev. 00

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 Molliau 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:	**Model No:**	**Variant:**
Advisa DR MRI™ SureScan™	A3DR01	MR Conditional

Test Report No.: 71366167

Model:	**Model No:**	**Variant:**
Ensura DR MRI™ SureScan™	EN1DR01	MR Conditional

Test Report No.: 713039269

Model:	**Model No:**	**Variant:**
Advisa SR MRI™ SureScan™	A3SR01	MR Conditional
Ensura SR MRI™ SureScan™	EN1SR01	MR Conditional

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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 039709 1199 Rev. 00

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 Programmer:	Implants to be programmed:
Application Software (external)	9995	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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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. 00

Product: **Implantable Pacemakers**

Test Report No.: 713095776

Model:	**Model No:**	**Variant:**
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	MR Conditional
Serena™ Quad CRT-P MRI SureScan™	W4TR05	MR Conditional
Solara™ Quad CRT-P MRI SureScan™	W4TR06	MR Conditional
Percepta™ CRT-P MRI SureScan™	W1TR04	MR Conditional
Serena™ CRT-P MRI SureScan™	W1TR05	MR Conditional
Solara™ CRT-P MRI SureScan™	W1TR06	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713095780

Model:	**Model No:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	SW040	2090 29901	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

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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. 00

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

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

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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 039709 1199 Rev. 00

Product: **Implantable Pacemakers**

Test Report No.: 713105247

Model:	**Model No:**	**Variant:**
Attesta™ DR MRI SureScan™	ATDR01	MR Conditional
Attesta™ L DR MRI SureScan™	ATDRL1	MR Conditional
Attesta™ S DR MRI SureScan™	ATDRS1	MR Conditional
Attesta™ SR MRI SureScan™	ATSR01	MR Conditional
Sphera™ DR MRI SureScan™	SPDR01	MR Conditional
Sphera™ L DR MRI SureScan™	SPDRL1	MR Conditional
Sphera™ SR MRI SureScan™	SPSR01	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713105248

Model:	**Model No:**	**For Programmer:**	**Implants to be programmed**
Application Software	SW043	2090 29901	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

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

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www.zlg.de
ZLG-BS-200.14.03

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 039709 1199 Rev. 00

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

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

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Osypka AG
Earl-H.-Wood-Straße 1
Rheinfelden
79618
Germany

Holds Certificate Number: **MD 613632**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019.
Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-30
Effective Date: 2021-03-11
Latest Revision Date: 2021-09-08
Expiry Date: 2024-03-10

...making excellence a habit.™

Certificate No: **MD 613632**

Location	Registered Activities
Osypka AG Earl-H.-Wood-Straße 1 Rheinfelden 79618 Germany	Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019. Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.
Osypka AG Gottlieb-Daimler-Str. 5 Rheinfelden 79618 Germany	Design, development, manufacturing, assembling and maintenance of medical devices for temporary stimulation and electrophysiology, permanent stimulation, HF-Ablation, interventional cardiology, medical components, neurology and contract sterilization services in accordance with EN ISO 11135:2014+A1:2019 Design, Entwicklung, Produktion, Montage und Wartung von Medizinprodukten aus den Bereichen Temporäre Stimulation und Elektrophysiologie, Permanente Stimulation, HF-Ablation, Interventionelle Kardiologie, Medical Components, Neurologie und Lohnsterilisation von Medizinprodukten nach EN ISO 11135:2014+A1:2019 als Dienstleistung.

Original Registration Date: 2016-06-30

Effective Date: 2021-03-11

Latest Revision Date: 2021-09-08

Expiry Date: 2024-03-10

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

Holds Certificate Number: **MD 94974**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and manufacture of vascular devices and heart valve delivery and loading systems. The manufacture of heart therapy/pacemaker delivery systems, biliary stents and delivery systems, nonactive implantable/non-implantable medical devices with drug coating/impregnation, catheter systems for renal denervation, venous occlusion systems, atherectomy systems, and implantable fixation systems. The loading & final assembly of transcatheter pacemaker systems. Provision of analytical test services for Medtronic Corporation facilities/sites.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2005-03-17
Latest Revision Date: 2021-08-04

Effective Date: 2021-08-09
Expiry Date: 2022-02-08

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Certificate No: **MD 94974**

Location	Registered Activities
Medtronic Ireland Parkmore Business Park West Galway Ireland	The design and manufacture of vascular devices and heart valve delivery and loading systems. The manufacture of heart therapy/pacemaker deliverysystems, biliary stents and delivery systems, nonactive implantable/non-implantable medical devices with drug coating/impregnation, catheter systems or renal denervation, venous occlusion systems, atherectomy systems, and implantable fixation systems. The loading & final assembly of transcatheter pacemaker systems. Provision of analytical test services for Medtronic Corporation facilities/sites.
Medtronic, Inc. 710 Medtronic Parkway Minneapolis Minnesota 55432 USA	Corporate Headquarters

Original Registration Date: 2005-03-17

Latest Revision Date: 2021-08-04

Effective Date: 2021-08-09

Expiry Date: 2022-02-08

Medtronic	Document Title: DoC-9529/9528	Document Number: MDT1951889
EC DECLARATION OF CONFORMITY	Insertable Cardiac Monitor (ICM) Reveal XT/DX, model 9529/9528	

Revision/History description	Revision level	Impl. Date
Declaration of Conformity was originally SQDM controlled by RA-290 version 1	-	01 Jun 2004
This Declaration of Conformity supersedes document RA290 version 1. Reveal models listed on RA290 were separated to their own individual DoCs. Updated to support AIMD Directive 90/385/EEC: Amendment 2007 and New Template	A	Upon Approval
Transfer CE marking from KEMA to TÜV SÜD Product Service as Notified Body.	B	30 Jun 2010
Update to reflect the details for the transition by serial, lot / batch number from KEMA (current notified body) to TUV (new notified body). Update compliance to EN ISO 11135-1	C	01 Octr 2010
Correct compliance statement to EN ISO 11135-1	D	12 Oct 2010
Update EC Quality System Certificate number	E	18 Nov 2010
Update for Reveal upgrade project include device firmware and software changes, functionality and labelling-added model 9528-previously included on DoC-9528-Reveal DX ICM. Note: This declaration replaces the old combined Reveal product system Declaration of Conformity. (DHF – QADoc: DSN003732)	2.0	19 Apr 2011
Conversion of Declaration of Conformity to the MRCS documentation system. Update to the latest standards and update to new template. Update to new EC Certificate and Quality System Certificate numbers. Removed notified body transfer attachment – transition was made from KEMA CE Mark to TuV CE Mark. First date of TuV marked package for European Packaged Product: July 29, 2010. First date of TuV marked package for Canadian Packaged Product: August 14, 2010.	2.0	05-Apr-2012
Updated to add new EC Quality System certificate number due to CE Renewal. New certificate (I1 13 02 39709 855) replaces certificate 9-761 and becomes effective May 2, 2013. As such, validity date updated to reflect May 2, 2013. Updated to new template.	3.0	26-Mar-2013
Update to ISO 14971:2012	4.0	26-Jul-2013
Updated to reflect new EC certificate number. New certificate (I7 15 06 39709 948) replaces certificate I7 12 02 39709 767 and becomes effective July 2, 2015. As such, validity date updated to reflect July 2, 2015.	5.0	25-Jun-2015
Updated standards: from EN ISO 11135-1:2007 to EN ISO 11135:2014; EN ISO 11607-1:2009 revision update to EN ISO 11607-1:2009+A1:2014. Added standards EN 60601-1:2006/A1:2013 and EN 60601-1-6:2010.	6.0	27-Oct-2016
Updated name of Senior Engineering Manager to Kiran Kuppuswamy. Updated standards: • from EN 60601-1-6:2010 to EN 60601-1-6:2010/Amd1:2013; Full Compliance • from EN 62366:2008 to EN 62366-1:2015	7.0	31-May-2017
Updated document template to revision AA. Updated Standards EN 60601-1-6:2010/Amd1:2013 to EN 60601-1-6:2010/A1:2015. Removed footnote on EN 62366-1:2015 to state full compliance.	8.0	16-Oct-2017
Added EN62304 to Attachment 1	9.0	25-Jan-2018
Updated to reflect new EC Quality System certificate number. New certificate (I1 18 03 39709 01185) replaces certificate I1 13 02 39709 855 and becomes effective May 2, 2018. As such, validity date updated to reflect May 2, 2018.	10.0	17-Apr-2018
Updated standards related to labelling and instructions for use: replaced EN 980 with EN ISO 15223-1, EN 1041, EN 45502-1. Updated formatting of number and date of issue and title of EN 62366-1.	11.0	24-Jan-2019
Replaced EN ISO 10993-1:2009/AC:2010 with ISO 10993-1:2018	12.0	18-Jul-2019
Update to new product certificate I7 039709 0948 (valid starting 08-Jun-2020) Added Amendment 1:2018 to EN ISO 11135:2014 Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020	13.0	02-Jun-2020
Update with cease manufacture information for 9528 Updated EN ISO 11135:2014+A1:2018 to 11135:2014+A1:2019 Changed EN 60601-1:2006+A1:2013 to EN 60601-1:2006+A12:2014. The change is due to the incorporation of technical corrigendum July 2014 (technical correction of Figure 12). Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date	AA	12-Oct-2020
Updated EC Quality System Certificate Number. New certificate (I1 039709 1185) replaces existing certificate and becomes effective 23 April 2021.	AB	18-May-2021
Updated standard compliance for EN ISO 14971, EN ISO 10993-1, and ISO 10993-7	AC	Upon Approval

Medtronic

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned : Model number: Variants:	Insertable Cardiac Monitor (ICM) – Reveal XT and Reveal DX 9529, 9528 Not Applicable
GMDN Code and Description	12103, Impedance Cardiograph
Classification, rule	AIMD
Conformity Assessment Route:	Annex 2.3 with Annex 2.4
EC Certificate number:	I7 039709 0948
EC Quality System Certificate:	I1 039709 1185
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC [1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***08-Jun-2020*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Jeffrey Chaput
Title: Sr. Engineering Manager

Signature: ***Refer to change record for electronic signature***
Available upon request: Non-electronic Date and Signature

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN 1041	2008+A1: 2013	Information supplied by the manufacturer of medical devices
EN 45502-1	2015	Implants for surgery - Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1	2003	Active implantable medical devices – Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
EN ISO 11135	2014+A1: 2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019	Medical devices – Application of risk management to medical devices
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
EN ISO 10993-7	2008+Amd.1:2019	Biological evaluation of medical devices - Part 7: Ethylene Oxide sterilization residuals
EN 60601-1 Clause 14	2006+ A12:2014	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-6	2010/A1: 2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
EN 62366-1	2015	Medical Devices – Part 1: Application of usability engineering to medical devices
EN 62304	2006+A1: 2015	Medical device software. Software life-cycle processes.

Attachment 2: Cease Manufacturing Information

The following product is no longer manufactured as shown by the information provided below.

Model Name	Model Number(s)	Last Manufacture Date	Last Manufacture Lot
Reveal DX	9528	05-May-2015	**RAB778109S**

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D-ZM-11321-01-00

Product Service

Certificate

No. Q5 039709 1202 Rev. 01

Holder of Certificate: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Facility(ies): Medtronic Bakken Research Center B.V.
Endepolsdomein 5, 6229 GW Maastricht, THE NETHERLANDS

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development and manufacturing of implantable leads and accessories and design and development of medical software. Translation of medical device software and product information**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713183409

Valid from: 2020-07-28
Valid until: 2023-05-31

Date, 2020-07-28

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis MN 55432, USA

Medtronic Inc.,
800 53rd Avenue NE, Columbia Heights MN 55421, USA

Medtronic Inc.
710 Medtronic Parkway N.E., Minneapolis, MN 55432, USA

Legal Entity with Management Oversight Responsibility for all Quality Related Matters

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

Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis, MN 55432, USA

Manufacturing of Leads and Accessories for Brady and Tachy IPGs, and fully absorbable surgical implants coated with ancillary medicinal substances

Medtronic Inc. Service Center
Sullivan Lake, 800 53rd Avenue NE, Columbia Heights, MN 55421, USA

Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Holder of Certificate: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713137849

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis MN 55432, USA

Medtronic Inc.,
800 53rd Avenue NE, Columbia Heights MN 55421, USA

Medtronic Inc.
710 Medtronic Parkway N.E., Minneapolis, MN 55432, USA

Legal Entity with Management Oversight Responsibility for all Quality Related Matters

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

Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis, MN 55432, USA

Manufacturing of Leads and Accessories for Brady and Tachy IPGs, and fully absorbable surgical implants coated with ancillary medicinal substances

Medtronic Inc. Service Center
Sullivan Lake, 800 53rd Avenue NE, Columbia Heights, MN 55421, USA

Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 039709 1219 Rev. 00

Holder of Certificate: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of Brady and Tachy IPGs, Pacemaker Delivery Systems, Leads and Accessories for Brady and Tachy IPGs, Ablation Systems/ Devices, Diagnostic and Ablation Catheters and their Accessories, Programmers for AIMDs, Application Software (external), External Pacemakers, Software and Hardware Systems for acquisition and management of ECG and cardiac device data, Implantable Monitoring and Recording Systems, and fully absorbable surgical implants coated with ancillary medicinal substances, and Service of Programmers for AIMDs, External Pacemakers, External Patient Monitors and RF Generators**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713137849

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-04-01

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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