Declaration of Conformity

Legal Identity:

FHC, Inc.
1201 Main Street
Bowdoin
Maine 04287
USA

Authorized Representative:

FHC Europe
(TERMOBIT PROD srl)
42A Barbu Vacarescu Str, 3rd Floor
Bucharest 020281 Sector 2
Romania
Tel: +40 21 230 7670
Fax: +40 031 405 0582

Equipment Identification

Type of Equipment: microTargeting™ Electrodes and Tubes

Model Number(s)	Description	Class	Rule
FC1002	microTargeting™ Single Insertion Electrode	III	6
FC1003	microTargeting™ Array Electrode	III	6
FC5000	microTargeting™ Electrode	III	6
FC2001	D.ZAP™ Array Insertion Electrode	III	6
FC2002	D.ZAP™ Single Insertion Electrode	III	6
FC2003	D.ZAP™ Electrode	III	6
FC2004	D.ZAP™ Electrode	III	6
FC1011	Single Electrode Insertion Tube Set	III	6
FC1012	Array Electrode Insertion Tube Set	III	6
FC1018	microTargeting™ Array Electrode Insertion Tube Set w/ Stylet	III	6
FC1019	microTargeting™ Lead Insertion Tube with Stylet	III	6
FC1036	microTargeting™ Single Electrode Insertion Tube Set	III	6
FC7140LI	Array Lead Insertion Tube with Stylet	III	6
FC8009	Star Array Electrode Insertion Tube with Stylet	III	6
FC9001	Sterile STar™ Array Insertion Tube 5x for Nexframe™ & STar™ Drive	III	6
FC9002	microTargeting™ Lead Insertion Tube with Stylet	III	6
FC9003	Star™ Single Electrode Insertion Tube	III	6
22670	microTargeting™ Array Insertion Electrodes	III	6
34680	microTargeting™ Single Insertion Electrode	III	6

We, FHC, Inc., hereby declare that the devices mentioned above comply with the Swedish National Board of Health and Welfare Regulation and guidelines on medical devices LVFS 2003:11 - transposing European Medical Devices Directive 93/42/EEC. Assessed by Intertek Semko AB, Notified Body No. 0413.

Conformity Assessment Procedures: Annex II

Name of Authorized Signatory: Kelly Moeykens
Position Held in Company: Quality System Officer and Regulatory Affairs Leader

Signature

Revision	Description	Edited by	Date
A	Initial Issue microTargeting™ Electrodes and Tubes DoC in new format	RO	1/4/16
B	Addition of reference to Notified body and EC certificate number	RO	2/20/16
C	Removal of Date of Validity	RO	7/19/16
D	Cert number correction	SM	6/1/2017
E	Addition of FC7140LI	SM	6/20/2017

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118279	13.0	Leffler, Theresa

Title: Model 3387, DBS Lead Kit for Deep Brain Stimulation

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr. Director, Quality and Reliability	02/26/2019 03:53:29 PM

EC Declaration of Conformity

Model 3387, DBS Lead Kit for Deep Brain Stimulation

Version	Description
13.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	DBS Lead Kit for Deep Brain Stimulation
Model number:	**3387**
Variants:	**3387-28, 3387-40**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 5 with Annex 3**
EC Certificate:	**I5 39709 01170**
EC Quality System Certificate:	**I2 18 02 39709 01156**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 3387, DBS Lead Kit for Deep Brain Stimulation

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date: **Place**: Medtronic Neuromodulation, Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: **Name**: [redacted]

[redacted] **and Reliability Entity**: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

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Identifier	Version	Author
NDHF1164-118280	8.0	Leffler, Theresa

Title: Model 3389, DBS Lead Kit for Deep Brain Stimulation

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	03/29/2018 02:13:12 PM

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

Version	Description
8.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	DBS Lead Kit for Deep Brain Stimulation
Model number:	**3389**
Variants:	**3389-15, 3389-28, 3389-40**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

Specific Harmonized Standards For EC Declaration of Conformity	
Number: Date of Issue	**Title**

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

3. R&TTED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the *Radio and Telecommunications Terminal Equipment Directive (R&TTED)* **1999/5/EC**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above test report(s) to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **1999/5/EC**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For R&TTED Declaration of Conformity	
Number: Date of Issue	**Title**

Validity DoC from date: **Place**: Medtronic Neuromodulation, Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: **Name**: **Daniel Rowenhorst**
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

4. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**

Validity DoC **Place**: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature date*

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

from date: Minneapolis, Minnesota, USA

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: ***refer to cover page for electronic signature***

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

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Identifier	Version	Author
NDHF1164-118409	10.0	Leffler, Theresa

Title: Model 3550-05, Percutaneous Extension and Tunneling Tools Accessory Kit

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 06:27:26 PM

EC Declaration of Conformity

Model 3550-05, Percutaneous Extension and Tunneling Tools Accessory Kit

Version	Description
10.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Percutaneous Extension and Tunneling Tools Accessory Kit
Model number:	**3550-05**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 3550-05, Percutaneous Extension and Tunneling Tools Accessory Kit

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

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Identifier	Version	Author
NDHF1164-118606	12.0	Leffler, Theresa

Title: Model 3755, DBS Tunneling Tool

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 06:32:15 PM

EC Declaration of Conformity

Model 3755, DBS Tunneling Tool

Version	Description
12.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	DBS Tunneling Tool
Model number:	**3755**
Variants:	**3755-40**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01172**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 3755, DBS Tunneling Tool

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118607	12.0	Leffler, Theresa

Title: Model 37086, DBS Extension

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	02/21/2019 09:36:54 PM

EC Declaration of Conformity

Model 37086, DBS Extension

Version	Description
12.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	DBS Extension
Model number:	**37086**
Variants:	**3708640, 3708660, 3708695**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01172**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 37086, DBS Extension

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118370	13.0	Leffler, Theresa

Title: Model 37612, ACTIVA RC

Pages: (including this page) 4

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 07:08:47 PM

EC Declaration of Conformity

Model 37612, Activa RC Neurostimulator

Version	Description
13.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Activa RC Neurostimulator
Model number:	**37612**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01164**
EC Quality System Certificate:	**I1 18 02 39709 01153**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 37612, Activa RC Neurostimulator

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date: **Place**: Medtronic Neuromodulation Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: [redacted]**d Reliability**

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 37612, Activa RC Neurostimulator

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity

Number: Date of Issue	Title
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date: **Place**: Medtronic Neuromodulation, Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]

Title: **Sr. Director, Quality and Reliability**

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118231	14.0	Leffler, Theresa

Title: Model 37642, Patient Programmer

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	10/23/2018 03:28:11 PM

EC Declaration of Conformity

Model 37642, Patient Programmer

Version	Description
14.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Patient Programmer
Model number:	**37642**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01167**
EC Quality System Certificate:	**I1 18 02 39709 01154**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 37642, Patient Programmer

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN 60601-1: 2006 +AC:2010 +A1:2013 +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 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 37642, Patient Programmer

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
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 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

EC Declaration of Conformity

Model 37642, Patient Programmer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**and Reliability Entity**: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118371	13.0	Leffler, Theresa

Title: Model 37651, Charging System

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Vice President Quality & Regulatory	12/13/2019 08:49:32 PM

EC Declaration of Conformity

Model 37651, Charging System

Version	Description
13.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Charging System
Model number:	**37651**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01167**
EC Quality System Certificate:	**I1 039709 1245**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 37651, Charging System

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
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 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Vice President, Quality & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 37651, Charging System

3. RED DECLARATION OF CONFORMITY

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

SPECIFIC STANDARDS FOR RED DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EC Declaration of Conformity

Model 37651, Charging System

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Vice President, Quality & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118392	11.0	Leffler, Theresa

Title: Model 64001, 1x4 Pocket Adaptor for Deep Brain Stimulation

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Vice President Quality & Regulatory	11/30/2019 01:42:38 AM

EC Declaration of Conformity

Model 64001, 1x4 Pocket Adaptor for Deep Brain Stimulation (DBS)

Version	Description
11.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	1x4 Pocket Adaptor for Deep Brain Stimulation (DBS)
Model number:	**64001**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 039709 1241**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 64001, 1x4 Pocket Adaptor for Deep Brain Stimulation (DBS)

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date: **Place**: Medtronic Neuromodulation Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: **N**[redacted]

[redacted]**& Regulatory**

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118394	11.0	Leffler, Theresa

Title: Model 64002, 2x4 Pocket Adaptor for Deep Brain Stimulation

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Vice President Quality & Regulatory	12/01/2019 07:56:53 PM

EC Declaration of Conformity

Model 64002, 2x4 Pocket Adaptor for Deep Brain Stimulation (DBS)

Version	Description
11.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	2x4 Pocket Adaptor for Deep Brain Stimulation (DBS)
Model number:	**64002**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 039709 1241**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 64002, 2x4 Pocket Adaptor for Deep Brain Stimulation (DBS)

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Vice President, Quality & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-126885	12.0	Leffler, Theresa

Title: Model 924256, Stimloc Burr Hole Cover

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Vice President Quality & Regulatory	12/01/2019 08:06:56 PM

EC Declaration of Conformity

Model 924256, Stimloc Burr Hole Cover

Version	Description
12.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Stimloc Burr Hole Cover
Model number:	**924256**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01172**
EC Quality System Certificate:	**I1 039709 1241**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 924256, Stimloc Burr Hole Cover

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
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 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Vice President, Quality & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Declaration of Conformity

Legal Identity:

FHC, Inc.
1201 Main Street
Bowdoin
Maine 04287
USA

Authorized Representative:

FHC Europe
(TERMOBIT PROD srl)
42A Barbu Vacarescu Str, 3rd Floor
Bucharest 020281 Sector 2
Romania
Tel: +40 21 230 7670
Fax:+40 031 405 0582

Equipment Identification

Type of Equipment: microTargeting™ Electrode and Tube accessories
microTargeting™ Electrode Cable

Model Number(s):	Description	Class	Rule
FC8011	Sterile STar™ Insertion Tube Extractor 5pk	I (STERILE)	I
FC1020	microTargeting™ Electrode Cable	I (STERILE)	I

We, FHC, Inc., hereby declare that the devices mentioned above comply with the Swedish National Board of Health and Welfare Regulation and guidelines on medical devices LVFS 2003:11 - transposing European Medical Devices Directive 93/42/EEC. Assessed by Intertek Semko AB, Notified Body No. 0413.

Conformity Assessment Procedure: Annex II

Name of Authorized Signatory: Kelly Moeykens
Position Held in Company Quality System Officer and Regulatory Affairs Leader

Signature

6/20/2017

[redacted]

Rev	Description of Change	Edited by	Date
A	Initial Release	CP	10/23/15
B	Removal of validity date	SM	6/20/2017

Declaration of Conformity

Legal Identity:

FHC, Inc.
1201 Main Street
Bowdoin
Maine 04287
USA

Authorized Representative:

FHC Europe
(TERMOBIT PROD srl)
42A Barbu Vacarescu Str, 3rd Floor
Bucharest 020281 Sector 2
Romania
Tel: +40 21 230 7670
Fax: +40 031 405 0582

Equipment Identification

Type of Equipment: microTargeting™ Electrodes and Tubes

Model Number(s)	Description	Class	Rule
FC1002	microTargeting™ Single Insertion Electrode	III	6
FC1003	microTargeting™ Array Electrode	III	6
FC5000	microTargeting™ Electrode	III	6
FC2001	D.ZAP™ Array Insertion Electrode	III	6
FC2002	D.ZAP™ Single Insertion Electrode	III	6
FC2003	D.ZAP™ Electrode	III	6
FC2004	D.ZAP™ Electrode	III	6
FC1011	Single Electrode Insertion Tube Set	III	6
FC1012	Array Electrode Insertion Tube Set	III	6
FC1018	microTargeting™ Array Electrode Insertion Tube Set w/ Stylet	III	6
FC1019	microTargeting™ Lead Insertion Tube with Stylet	III	6
FC1036	microTargeting™ Single Electrode Insertion Tube Set	III	6
FC7140LI	Array Lead Insertion Tube with Stylet	III	6
FC8009	Star Array Electrode Insertion Tube with Stylet	III	6
FC9001	Sterile STar™ Array Insertion Tube 5x for Nexframe™ & STar™ Drive	III	6
FC9002	microTargeting™ Lead Insertion Tube with Stylet	III	6
FC9003	Star™ Single Electrode Insertion Tube	III	6
22670	microTargeting™ Array Insertion Electrodes	III	6
34680	microTargeting™ Single Insertion Electrode	III	6

We, FHC, Inc., hereby declare that the devices mentioned above comply with the Swedish National Board of Health and Welfare Regulation and guidelines on medical devices LVFS 2003:11 - transposing European Medical Devices Directive 93/42/EEC. Assessed by Intertek Semko AB, Notified Body No. 0413.

Conformity Assessment Procedures: Annex II

Name of Authorized Signatory: Kelly Moeykens
Position Held in Company: Quality System Officer and Regulatory Affairs Leader

Signature

6/20/2017

[redacted]

Revision	Description	Edited by	Date
A	Initial Issue microTargeting™ Electrodes and Tubes DoC in new format	RO	1/4/16
B	Addition of reference to Notified body and EC certificate number	RO	2/20/16
C	Removal of Date of Validity	RO	7/19/16
D	Cert number correction	SM	6/1/2017
E	Addition of FC7140LI	SM	6/20/2017

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118279	13.0	Leffler, Theresa

Title: Model 3387, DBS Lead Kit for Deep Brain Stimulation

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr. Director, Quality and Reliability	02/26/2019 03:53:29 PM

EC Declaration of Conformity

Model 3387, DBS Lead Kit for Deep Brain Stimulation

Version	Description
13.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	DBS Lead Kit for Deep Brain Stimulation
Model number:	**3387**
Variants:	**3387-28, 3387-40**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 5 with Annex 3**
EC Certificate:	**I5 39709 01170**
EC Quality System Certificate:	**I2 18 02 39709 01156**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 3387, DBS Lead Kit for Deep Brain Stimulation

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: [redacted]

Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118280	8.0	Leffler, Theresa

Title: Model 3389, DBS Lead Kit for Deep Brain Stimulation

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	03/29/2018 02:13:12 PM

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

Version	Description
8.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	DBS Lead Kit for Deep Brain Stimulation
Model number:	**3389**
Variants:	**3389-15, 3389-28, 3389-40**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

Specific Harmonized Standards For EC Declaration of Conformity	
Number: Date of Issue	**Title**

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

3. R&TTED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the *Radio and Telecommunications Terminal Equipment Directive (R&TTED)* **1999/5/EC**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above test report(s) to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **1999/5/EC**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For R&TTED Declaration of Conformity	
Number: Date of Issue	**Title**

Validity DoC from date: **Place**: Medtronic Neuromodulation, Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: **Name**: [redacted]**t**
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

4. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**

Validity DoC **Place**: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature date*

EC Declaration of Conformity

Model 3389, DBS Lead Kit for Deep Brain Stimulation

from date: Minneapolis, Minnesota, USA

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]t
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: ***refer to cover page for electronic signature***

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118230	12.0	Leffler, Theresa

Title: Model 37601, Activa PC Neurostimulator

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	03/29/2018 02:24:36 PM

EC Declaration of Conformity

Model 37601, Activa PC Neurostimulator

Version	Description
12.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Activa PC Neurostimulator
Model number:	**37601**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01164**
EC Quality System Certificate:	**I1 18 02 39709 01153**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

Specific Harmonized Standards For EC Declaration of Conformity

EC Declaration of Conformity

Model 37601, Activa PC Neurostimulator

Number: Date of Issue	Title
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer
EN 62304: 2006 +AC:2008	Medical device software - Software life-cycle processes
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 37601, Activa PC Neurostimulator

3. R&TTED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the *Radio and Telecommunications Terminal Equipment Directive (R&TTED)* **1999/5/EC**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above test report(s) to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **1999/5/EC**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For R&TTED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

4. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**

EC Declaration of Conformity

Model 37601, Activa PC Neurostimulator

SPECIFIC STANDARDS FOR RED DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**nd Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118227	13.0	Leffler, Theresa

Title: Model 37602, Activa SC Multi-program Neurostimulator

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	03/29/2018 02:47:52 PM

EC Declaration of Conformity

Model 37602, Activa SC Multi-program Neurostimulator

Version	Description
13.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Activa SC Multi-program Neurostimulator
Model number:	**37602**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01149**
EC Quality System Certificate:	**I1 18 02 39709 01153**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

Specific Harmonized Standards For EC Declaration of Conformity	
Number: Date of Issue	**Title**

EC Declaration of Conformity

Model 37602, Activa SC Multi-program Neurostimulator

EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer
EN 62304: 2006 +AC:2008	Medical device software - Software life-cycle processes
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**nd Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 37602, Activa SC Multi-program Neurostimulator

3. R&TTED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the *Radio and Telecommunications Terminal Equipment Directive (R&TTED)* **1999/5/EC**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above test report(s) to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **1999/5/EC**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For R&TTED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer

Validity DoC from date: **Place**: Medtronic Neuromodulation, Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: **Name**: [redacted]

[redacted]**nd Reliability**

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

4. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**

EC Declaration of Conformity

Model 37602, Activa SC Multi-program Neurostimulator

SPECIFIC STANDARDS FOR RED DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: D[redacted]
[redacted]**nd Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118228	17.0	Leffler, Theresa

Title: Model 37603, Activa SC Multi-program Neurostimulator

Pages: (including this page) 4

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Vice President Quality & Regulatory	12/13/2019 09:13:10 PM

EC Declaration of Conformity

Model 37603, Activa SC Multi-program Neurostimulator

Version	Description
17.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Activa SC Multi-program Neurostimulator
Model number:	**37603**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01149**
EC Quality System Certificate:	**I1 039709 1242**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 37603, Activa SC Multi-program Neurostimulator

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
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 ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

N[redacted]

Title: **Vice President, Quality & Regulatory**

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 37603, Activa SC Multi-program Neurostimulator

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity

Number: Date of Issue	Title
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

Validity DoC from date: **Place**: Medtronic Neuromodulation, Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: **N**[redacted]

Title: **Vice President, Quality & Regulatory**

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118430	10.0	Leffler, Theresa

Title: Model 3550-29, Octopolar In-Line Neurostimulator Plug & 1x8 Low-Profile Closed Boot Accessory Kit

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 06:42:54 PM

EC Declaration of Conformity

Model 3550-29, Octopolar_In-Line Neurostimulator Plug & 1x8 Low-Profile Closed Boot Accessory Kit

Version	Description
10.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Octopolar_In-Line Neurostimulator Plug & 1x8 Low-Profile Closed Boot Accessory Kit
Model number:	**3550-29**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 3550-29, Octopolar_In-Line Neurostimulator Plug & 1x8 Low-Profile Closed Boot Accessory Kit

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

N[redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118433	10.0	Leffler, Theresa

Title: Model 3550-38, 1x8 Tunneling Tool Accessory Kit

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 06:43:33 PM

EC Declaration of Conformity

Model 3550-38, 1x8 Tunneling Tool Accessory Kit

Version	Description
10.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	1x8 Tunneling Tool Accessory Kit
Model number:	**3550-38**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 3550-38, 1x8 Tunneling Tool Accessory Kit

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**nd Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

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Identifier	Version	Author
NDHF1164-118369	10.0	Leffler, Theresa

Title: Model 37092, Antenna

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 07:08:26 PM

EC Declaration of Conformity

Model 37092, Antenna

Version	Description
10.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Antenna
Model number:	**37092**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01167**
EC Quality System Certificate:	**I1 18 02 39709 01154**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 37092, Antenna

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 60601-1-11: 2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN 60601-1: 2006 +AC:2010 +A1:2013 +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 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date: **Place**: Medtronic Neuromodulation Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: **Name**: [redacted]

[redacted]**nd Reliability**

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-128403	11.0	Leffler, Theresa

Title: Model 97702, PrimeAdvanced SureScan MRI

Pages: (including this page) 4

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 06:45:50 PM

EC Declaration of Conformity

Model 97702, PrimeAdvanced SureScan MRI

Version	Description
11.0	Final Version – updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	PrimeAdvanced SureScan MRI
Model number:	**97702**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01166**
EC Quality System Certificate:	**I1 18 02 39709 01153**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 97702, PrimeAdvanced SureScan MRI

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]t
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 97702, PrimeAdvanced SureScan MRI

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-128410	12.0	Leffler, Theresa

Title: Model 97740, Patient Programmer

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 06:33:37 PM

EC Declaration of Conformity

Model 97740, Patient Programmer

Version	Description
12.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Patient Programmer
Model number:	**97740**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01166**
EC Quality System Certificate:	**I1 18 02 39709 01154**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 97740, Patient Programmer

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 60601-1-11: 2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN 60601-1: 2006 +AC:2010 +A1:2013 +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 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**nd Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 97740, Patient Programmer

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 60601-1-11: 2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
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 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

EC Declaration of Conformity

Model 97740, Patient Programmer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-125646	9.0	Leffler, Theresa

Title: Model 97792, Injex Bi-Wing Anchor

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	03/29/2018 07:23:35 PM

EC Declaration of Conformity

Model 97792, Injex Bi-Wing Anchor

Version	Description
9.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Injex Bi-Wing Anchor
Model number:	**97792**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01172**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 97792, Injex Bi-Wing Anchor

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 45502-1: 1997	Active Implantable Medical Devices - Part 1 - General requirements for safety, marking and information to be provided by the manufacturer
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118768	10.0	Leffler, Theresa

Title: Model 355531, Multi-Lead Trialing Cable

Pages: (including this page) 4

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	04/04/2018 09:07:53 PM

EC Declaration of Conformity

Model 355531, Multi-Lead Trialing Cable

Version	Description
10.0	R&TTED and RED sections removed

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Multi-Lead Trialing Cable
Model number:	**355531**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**Class I, sterile, rule 1**
Conformity Assessment Route:	**Annex V with Annex VII**
EC Certificate:	**NA**
EC Quality System Certificate:	**G2S 18 02 39709 01151**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 355531, Multi-Lead Trialing Cable

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 60601-1-2: 2007 +AC:2010	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - requirements and tests
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN 60601-1-11: 2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
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 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EC Declaration of Conformity

Model 355531, Multi-Lead Trialing Cable

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**d Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-128420	10.0	Leffler, Theresa

Title: Model 977A275, Vectris SureScan MRI Lead kit

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 06:59:36 PM

EC Declaration of Conformity

Model 977A275, Vectris SureScan MRI Lead kit

Version	Description
10.0	Final Version – updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Vectris SureScan MRI Lead kit
Model number:	**977A275**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01166**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 977A275, Vectris SureScan MRI Lead kit

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]t
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-128421	10.0	Leffler, Theresa

Title: Model 977A290, Vectris SureScan MRI Lead kit

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 07:00:26 PM

EC Declaration of Conformity

Model 977A290, Vectris SureScan MRI Lead kit

Version	Description
10.0	Final Version – updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Vectris SureScan MRI Lead kit
Model number:	**977A290**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01166**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 977A290, Vectris SureScan MRI Lead kit

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering 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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-118341	10.0	Leffler, Theresa

Title: Model 37081, Extension Kit

Pages: (including this page) 3

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 07:14:17 PM

EC Declaration of Conformity

Model 37081, Extension Kit

Version	Description
10.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Extension Kit
Model number:	**37081**
Variants:	**37081-20, 37081-40, 37081-60**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 18 02 39709 01171**
EC Quality System Certificate:	**I1 18 02 39709 01152**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 37081, Extension Kit

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11607-1: 2009 +A1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-159917	5.0	Leffler, Theresa

Title: Model 97715, Intellis Implantable Neurostimulator with AdaptiveStim Technology

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	08/06/2018 07:07:47 PM

EC Declaration of Conformity

Model 97715, Intellis Implantable Neurostimulator with AdaptiveStim Technology

Version	Description
5.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Intellis Implantable Neurostimulator with AdaptiveStim Technology
Model number:	**97715**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 17 05 39709 01090**
EC Quality System Certificate:	**I1 18 02 39709 01153**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 97715, Intellis Implantable Neurostimulator with AdaptiveStim Technology

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
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 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14971: 2012	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
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
EN 1041: 2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 11607-2: 2006 +A1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification [redacted]

Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 97715, Intellis Implantable Neurostimulator with AdaptiveStim Technology

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 301 839: v2.1.1	Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonized Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-27: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P) operating in the 402 MHz to 405 MHz bands; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

EC Declaration of Conformity

Model 97715, Intellis Implantable Neurostimulator with AdaptiveStim Technology

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer: [redacted]d Reliability

Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1164-159989	8.0	Leffler, Theresa

Title: Model 97725, Wireless External Neurostimulator

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Vice President Quality & Regulatory	12/01/2019 07:58:13 PM

EC Declaration of Conformity

Model 97725, Wireless External Neurostimulator

Version	Description
8.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Wireless External Neurostimulator
Model number:	**97725**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**Class IIb, rule 9**
Conformity Assessment Route:	**Annex II.3**
EC Certificate:	**NA**
EC Quality System Certificate:	**G1 039709 1238**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 97725, Wireless External Neurostimulator

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
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 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11135: 2014	Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 10993-7: 2008 +AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices

EC Declaration of Conformity

Model 97725, Wireless External Neurostimulator

Validity DoC from date: **Place**: Medtronic Neuromodulation Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer: [redacted]
Title: **Vice President, Quality & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 300 328: v2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17: v3.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EC Declaration of Conformity

Model 97725, Wireless External Neurostimulator

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Vice President, Quality & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

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Identifier	Version	Author
NDHF1164-159916	8.0	Leffler, Theresa

Title: Model 97745, Controller

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Vice President Quality & Regulatory	11/23/2019 02:06:55 AM

EC Declaration of Conformity

Model 97745, Controller

Version	Description
8.0	Final Version - updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Controller
Model number:	**97745**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 039709 1195**
EC Quality System Certificate:	**I1 039709 1245**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 97745, Controller

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
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 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 45502-1: 2015	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: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**ty & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 97745, Controller

3. RED DECLARATION OF CONFORMITY

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

SPECIFIC STANDARDS FOR RED DECLARATION OF CONFORMITY

Number: Date of Issue	Title
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 301 489-27: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P) operating in the 402 MHz to 405 MHz bands; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 489-17: v3.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 839: v2.1.1	Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonized Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 300 328: v2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 45502-1: 2015	Implants for surgery — Active implantable medical devices. Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

EC Declaration of Conformity

Model 97745, Controller

SPECIFIC STANDARDS FOR RED DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 60601-1: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**y & Regulatory**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature

Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

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Identifier	Version	Author
NDHF1164-159915	6.0	Leffler, Theresa

Title: Model 97755, Recharger

Pages: (including this page) 5

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
[redacted]	Sr Director, Quality and Reliability	12/17/2018 04:35:37 PM

EC Declaration of Conformity

Model 97755, Recharger

Version	Description
6.0	Final version updated per current content of database.

1. General Device Information

General Device Information	
Manufacturer:	**Medtronic Inc.** 710 Medtronic Parkway Minneapolis MN 55432 USA
Description of device concerned:	Recharger
Model number:	**97755**
Variants:	**NA**

2. EC Declaration of Conformity

Specific EC Declaration of Conformity Information	
EC Representative:	**Medtronic B.V.** Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Classification, rule:	**AIMD**
Conformity Assessment Route:	**Annex 2 excluding (4) with Annex 2.4**
EC Certificate:	**I7 39709 1195**
EC Quality System Certificate:	**I1 18 02 39709 01154**
Name of Notified Body:	**TÜV SÜD PS GmbH** **Ridlerstrasse 65** **D-80339 München** **Germany**
Notified Body Identification Number:	**0123**

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**, including amendments issued in the years following, which apply to them.

This declaration is supported by the above 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.

EC Declaration of Conformity

Model 97755, Recharger

SPECIFIC HARMONIZED STANDARDS FOR EC DECLARATION OF CONFORMITY	
Number: Date of Issue	**Title**
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62304: 2006 +A1:2015	Medical device software – Software life-cycle processes
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
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 1041: 2008 +A1:2013	Information supplied by the manufacturer of 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
EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 45502-1: 2015	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: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 10993-1: 2009 (Oct) +AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*
Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
Title: **Sr. Director, Quality and Reliability**
Entity: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*
Available upon request: Non-electronic Signature

EC Declaration of Conformity

Model 97755, Recharger

3. RED Declaration of Conformity

Statement:

We, Medtronic Neuromodulation, declare under our sole responsibility that the products described in section 1 to which this document relates is in conformity with the essential requirements and other relevant requirements of the Radio Equipment Directive (RED) **2014/53/EU**, including amendments issued in the years following, which apply to them.

This declaration is to provide evidence to the presumption of conformity to the essential requirements of the following Articles of the Directive **2014/53/EU**:

- Article 3.1.a (Health & Safety)
- Article 3.1.b (EMC)
- Article 3.2 (Use of Spectrum)

The following harmonized standards and/or other normative documents are those to which the product's conformance is declared. This declaration applies to the product's distribution from the signature date forward.

Specific Standards For RED Declaration of Conformity	
Number: Date of Issue	**Title**
EN 60601-1-11: 2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
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 301 489-31: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P); Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 302 195: v2.1.1	Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
EN 301 489-1: v2.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 45502-1: 2015	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: 2006 +AC:2010 +A1:2013 +A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EC Declaration of Conformity

Model 97755, Recharger

Validity DoC from date:

Place: Medtronic Neuromodulation
Minneapolis, Minnesota, USA

Date: *refer to cover page for electronic signature date*

Available upon request: Non-electronic Date of Signature

Identification of signer:

Name: [redacted]
[redacted]**and Reliability Entity**: Medtronic Neuromodulation

Date: *refer to cover page for electronic signature*

Available upon request: Non-electronic Signature