



Product Service

EC Certificate

EC Design-Examination Certificate

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

No. 17 12 06 39709 814

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

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

Product: **Leads for Muscle-/Neurostimulators and
their auxiliary components**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713005371

Valid from: 2012-08-30

Valid until: 2017-08-29

Date, 2012-07-27

Hans-Heiner Junker



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

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No. 17 12 06 39709 814**Model(s):** see attachment**Parameters:** ./.**Facility(ies):**
Medtronic Neuromodulation
800 53rd Ave. N.E., Minneapolis MN 55421, USA

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

Medtronic Neuromodulation
7000 Central Ave. N.E., Minneapolis MN 55432, USA**Design
Facility(ies):**
Medtronic Neuromodulation
800 53rd Ave. N.E., Minneapolis MN 55421, USA

Medtronic Neuromodulation
7000 Central Ave. N.E., Minneapolis MN 55432, USA



**Attachment for Certificate no I7 12 06 39709 814
dated 2012-08-30**

**Product: Leads for Muscle- / Neurostimulators and their
aux. components**

Test Report No.: 70031812

Model:	Model No:
DBS™ Lead Kit for Deep Brain Stimulation	3389
DBS™ Extension Kit for Deep Brain Stimulation	7482
Pisces Quad Compact™ Lead Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	3887
Specify® Lead Kit for Spinal Cord Stimulation	3998
Boots and Anchors Accessory Kit	3550-01
Wrenches and Screws Accessory Kit	3550-02
Twist Lock Screening Cable Accessory Kit	3550-03
Epidural Needle Accessory Kit	3550-04
Percutaneous Extension and Tunneling Tools Accessory Kit	3550-05
Tunneling Tools Accessory Kit	3550-06
Alligator Clip Screening Cable Accessory Kit	3550-07
Stylet Accessory Kit	3550-08
Plug and Closed Boot Accessory Kit	3550-09
Pisces Quad® Percutaneous Lead Revision Accessory Kit	3550-10
Extension Passer Accessory Kit	3555



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dated 2012-08-30**

Model:	Model No:
InterStim [®] Unipolar Lead Kit for Intramuscular Stimulation	4350
Enterra [™] Therapy Unipolar Lead for Gastric Electrical Stimulation	4351
InterStim [®] Quadripolar Lead for electrical Stimulation	3889/3093
InterStim [®] Insulated extension to connect the Lead to the Neurostimulator	3095
Lead Introducer	042294
Lead Introducer Kit	3550-18
Test Report No.: 70030456	
Model:	Model No:
Pisces Z Quad Lead Revision Accessory Kit	3550-22
Pisces Z Quad Lead Revision Accessory Kit	3550-23
EZ Anchor Accessory Kit	3550-16



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Test Report No.: 70031732

Model:	Model No:
Low Impedance Quadripolar Extension Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	7489
Boots and Anchors Accessory Kit for SCS and PNS	3550-24
Boots Accessory Kit for DBS™	3550-25

Test Report No.: 70053254

Model:	Model No:
Resume® TL Lead Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	3986A
SymMix® Lead Kit for Spinal Cord Stimulation	3982A
On-Point® Lead Kit for Peripheral Nerve Stimulation	3987A

Test Report No.: 70080226

Model:	Model No:
2x4 Hinged Lead Kit for Spinal Cord Stimulation	3999

Test Report No.: 70087323

Model:	Model No:
Octapolar In-line Neurostimulator Plug and 1x8 Low Profile Closed Boot Accessory Kit	3550-29



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Test Report No.: 70087330

Model:	Model No:
1x8 Low Impedance Lead Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	3777
1x8 Low Impedance Lead Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	3877
1x8 Compact Low Impedance Lead Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	3778
1x8 Compact Low Impedance Lead Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	3878
1x8 Lead Revision Accessory Kit	3550-26
1x8 Lead Revision Accessory Kit	3550-27
Epidural Needle Accessory Kit	3550-28
Epidural Needle Accessory Kit	3550-32

Test Report No.: 70086166

Model:	Model No:
1x8 Extension Tunneling Tool Accessory Kit	3550-38
1x8 Extension Tunneling Tool Accessory Kit	3550-60
1x8 Low Impedance Extension Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	37081
1x8 Low Impedance Extension Kit for Spinal Cord Stimulation and Peripheral Nerve Stimulation	7472



**Attachment for Certificate no I7 12 06 39709 814
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Test Report No.: 70106396

Model:

Single Quadripolar Extension Kit (8-4) for Spinal
Cord Stimulation and Peripheral Nerve Stimulation

Model No:

37083

Test Report No.: 70106857

Model:

Titan Anchor Accessory Kit

Model No:

3550-39

Test Report No.: 70107523

Model:

1x8 SC Low Impedance Lead Kit for Spinal Cord
Stimulation and Peripheral Nerve Stimulation

Model No:

3776

1x8 SC Low Impedance Lead Kit for Spinal Cord
Stimulation and Peripheral Nerve Stimulation

3876

Test Report No.: 70116182

Model:

Dual Quadripolar Extension Kit (8-2-4) for Spinal
Cord Stimulation and Peripheral Nerve Stimulation

Model No:

37082



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Test Report No.: 71313371

Model:	Model No:
DBS™ Extension Kit for Deep Brain Stimulation	7482A
Tunneling Tool Accessory Kit	3655

Test Report No.: 71321966

Model:	Model No:
Specify™ 5-6-5 Lead Kit for Spinal Cord Stimulation	39565

Test Report No.: 71336435

Model:	Model No:
DBS™ Lead Kit for Deep Brain Stimulation	3387S
DBS™ Lead Kit for Deep Brain Stimulation	3389S

Test Report No.: 71339199

Model:	Model No:
DBS™ Extension Kit for Deep Brain Stimulation	37085

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Test Report No.: 71347675

Model:

Interstim Torque Wrench and Boot Accessory Kit

Model No:

3550-80

Test Report No.: 71349970

Model:

Passing Elevator Accessory Kit

Model No:

3550-P4

Test Report No.: 71349973

Model:

Specify™ 2x8 Lead Kit for Spinal Cord Stimulation

Model No:

39286

Test Report No.: 71353092

Model:

1x4 Pocket Adaptor for Deep Brain Stimulation (DBS)

Model No:

64001

2x4 Pocket Adaptor for Deep Brain Stimulation (DBS)

64002

1x4 Pocket Adaptor for Spinal Cord Stimulation (SCS)

74001

2x4 Pocket Adaptor for Spinal Cord Stimulation (SCS)

74002



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**Attachment for Certificate no I7 12 06 39709 814
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Test Report No.: 71351244

Model:

Percutaneous Lead Introducer Accessory Kit

Model No:

3550-63

Test Report No.: 71351155

Model:

DBS™ Lead Kit for Deep Brain Stimulation

Model No:

3391

DBS™ Lead Kit for Deep Brain Stimulation

3391S

Test Report No.: 71357678

Model:

Curved-tip Epidural Needle accessory kit

Model No:

3550-14

Curved-tip Epidural Needle accessory kit

3550-43

Munich, CRT2, 2012-08-30

Hans-Heiner Junker
Certification Medical Technology