ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Design-Examination Certificate

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

No. I7 12 06 39709 820

Manufacturer:

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

EC-Representative:

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

Product:

Implantable Muscle- / Neurostimulator Systems

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

Report no.: 713002176

Valid from: 2012-08-30
Valid until: 2017-08-29

Date, 2012-07-27

Hans-Heiner Junker

492790

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

TÜV®

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Product Service

EC Certificate
EC Design-Examination Certificate

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

No. I7 12 06 39709 820

Model(s): see attachment

Parameters: ./.

Facility(ies):

Medtronic Neuromodulation
800 53rd Ave. N.E., Minneapolis MN 55421, USA

Medtronic Puerto Rico Operations Co., Juncos
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR 00777, USA

Medtronic Europe Sàrl
Route du Molliau 31, Case Postale, 1131 Tolochenaz, SWITZERLAND

Medtronic 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

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Product Service

Attachment for Certificate no I7 12 06 39709 820
dated 2012-08-30

Product: **Implantable Muscle-/ Neurostimulator Systems**

Test Report No.: 70031812

Model:	**Model No:**
Itrel® 3	7425
Synergy™	7427
Kinetra™	7428
Synergy™ Neurostimulation System	7729 (Contents: One Synergy™ Model 7427 Neurostimulator One Synergy™ EZ Model 7435 Patient Programmer)
Synergy Versitrel™	7427V
InterStim®	3023

Test Report No.: 70031203

Model:	**Model No:**
InterStim® TWIN	7427T

Test Report No.: 70031725

Model:	**Model No:**
Enterra™ Therapy	3116

Test Report No.: 70087323

Model:	**Model No:**
Restore™	37711

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Product Service

Attachment for Certificate no I7 12 06 39709 820
dated 2012-08-30

Test Report No.: 70110909

Model:	**Model No:**
InterStim® II	3058

Test Report No.: 71309784

Model:	**Model No:**
PrimeADVANCED™	37702
RestoreADVANCED™	37713

Test Report No.: 71326257

Model:	**Model No:**
RestoreULTRA™	37712

Test Report No.: 71339211

Model:	**Model No:**
Activa® RC	37612

Test Report No.: 71340299

Model:	**Model No:**
Activa® PC	37601

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Product Service

Attachment for Certificate no I7 12 06 39709 820
dated 2012-08-30

Test Report No.: 71364014

Model:	**Model No:**
RestoreSensor™	37714

Test Report No.: 713002850

Model:	**Model No:**
Itrel®4	37703
Itrel®4	37704

Munich, CRT2, 2012-08-20

Hans-Heiner Junker
Certification Medical Technology

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