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

Product Service

EC Design Examination Certificate

(Annex 2, section 4 of the Directive 90/385/EEC on Active Implantable Medical Devices)

No. I7 10 05 39709 657

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 aforementioned devices according to Annex 2, section 4 of the Directive 90/385/EEC on Active Implantable Medical Devices. This design of the devices conforms to the provisions of this Directive. For marketing of the product an additional Annex 2.3 certificate is mandatory. See also notes overleaf.

Report no.: 71365833

Valid until: 2012-08-29

427305

Date, 2010-06-30

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 90/385/EEC concerning Active Implantable Medical Devices with identification no. 0123.

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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EC-Design Examination Certificate

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No. I7 10 05 39709 657

Model(s): **see attachment**

Parameters: ./.

Facility(ies):

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

Medtronic Puerto Rico Operations Co., MedRel
Road #31, km24 hm4, PR 00777 Juncos, USA

Medtronic Europe Sàrl
Route du Molliau 31,Case Post., 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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Attachment for Certificate No. I7 10 05 39709 657
from 2010-06-30

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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Attachment for Certificate No. I7 10 05 39709 657
from 2010-06-30

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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Attachment for Certificate No. I7 10 05 39709 657
from 2010-06-30

Test Report No.: 71364014

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

Munich, CRT2, 2010-06-30

Hans-Heiner Junker
Certification Medical Technology

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