



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 815

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 Infusion Pumps
Accessories for implantable Infusion
Pumps**

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.: 713000257

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 815

Model(s): see attachment

Parameters: ./.

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

Medtronic Neuromodulation
800 53rd Ave. N.E., Minneapolis MN 55421, 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 815
dated 2012-08-30**

Product: Implantable Infusion Pumps

Test Report No.: 70035757

Model:	Model No:
SynchroMed® II Programmable Pump	8637

Product: Accessories for Implantable Infusion Pumps

Test Report No.: 70031812

Model:	Model No:
IsoMed / Anschütz IP20.1 Catheter Access Port Kit	8543
IsoMed® Refill Kit	8553

Test Report No.: 70035739

Model:	Model No:
Refill Kit	8555

Munich, CRT2, 2012-08-30

Hans-Heiner Junker
Certification Medical Technology