



Product Service

EC Design Examination Certificate

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

No. I7 07 08 39709 514

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:

**Catheters for Implantable
Infusion Pumps and their auxiliary
components**

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.:

71320957

Valid until:

2012-08-29

**Date:** 2007-08-30

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

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Model(s): **see attachment**

Facility(ies): Medtronic Neuromodulation
800 53rd Ave. N.E., Minneapolis MN 55421, USA

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



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Attachment for Certificate No. I7 07 08 39709 514
from 2007-08-30

Product: Catheters for Implantable Infusion Pumps and their
auxiliary components

Test Report No.: 70031812

Model:

InDura® Closed-Tip Intrathecal Catheter

Model No.:

8711

Test Report No.: 70035872

Model:

Catheter Passer

Model No:

8583, 8586

Test Report No.: 70037658

Model:

Connector Accessory Kit

Model No:

8575, 8577



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**Attachment for Certificate No. I7 07 08 39709 514
from 2007-08-30**

Test Report No.: 70118010

Model:

Indura 1P

Intrathecal Catheter

Sutureless Pump Connector Revision Kit

Intrathecal Catheter Pump Segment Revision Kit

Intrathecal Catheter Spinal Segment Revision Kit

Model No:

8709SC

8731SC

8578

8596SC

8598 A

Munich, CRT2, 2007-08-30

Reiner Krumme