



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 10 70692 015

Manufacturer: **Greatbatch Medical**
 2300 Berkshire Lane North
 Minneapolis MN 55441
 USA

EC-Representative: **Medical Device Safety Service GmbH**
 Schiffgraben 41
 30175 Hannover
 GERMANY

Product: **Leads for Brady IPGs and their auxiliary components
 Implantable Lead Adapters for AIMDs**

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.: DM1204140

Valid from: 2012-10-31

Valid until: 2017-10-24

Date, 2012-10-31

Hans-Heiner Junker



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

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Model(s): see attachment

Parameters: ./.

Facility(ies): Greatbatch Medical
2300 Berkshire Lane North, Minneapolis MN 55441, USA

Design Facility(ies): Greatbatch Medical
2300 Berkshire Lane North, Minneapolis MN 55441, USA



Product Service

Attachment for Certificate No. I7 12 10 70692 015
dated 2012-10-31

Product: Leads for Brady IPGs & their auxiliary components

Test Report No.: 71328003

Model:	Model No.:
Myopore® Unipolar Sutureless Myocardial Pacing Lead	511111, 511112
Myopore® Bipolar Sutureless Myocardial Pacing Lead	511211, 511212, 511210
Myodex™ Steriod-Eluting, Bipolar Sutureless Myocardial Pacing Lead	1084T
FasTac® Introducer	
FasTac Flex® Steerable Lead Implant Tool	6201FAS

Product: Implantable Lead Adapters for AIMDs

Test Report No.: 71328003

Model:	Model No.
Lead Adapter (unipolar)	501203, 501204
Lead Adapter (bipolar)	501205, 501206, 501214
Cap and Sleeve Kit (unipolar)	501207

Munich, CRT2, 2012-10-31

Hans-Heiner Junker