



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 17 11 70692 022

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



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

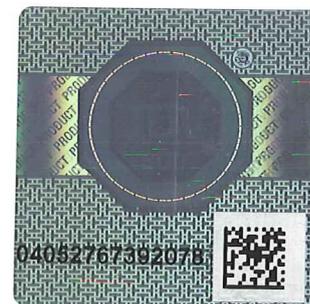
Product: **Accessories for Implantable Leads for AIMDs
Leads for Brady IPGs and their auxiliary
components**

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.: 72127489

Valid from: 2017-12-22

Valid until: 2022-10-24



Date, 2017-12-22

Stefan Preiß

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

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No. 17 17 11 70692 022**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 17 11 70692 022
dated 2017-12-22

Product: Accessories for Implantable Leads for AIMDs
Leads for Brady IPGs and their auxiliary components

Test Report No.: 71328003

| Model: | Model No.: |
|--|--|
| Myopore® Bipolar Sutureless Pacing Lead | 511210, 511211, 511212 |
| MyoDex Steroid-Eluting Bipolar Sutureless Myocardial Pacing Lead | 1084T |
| Lead Adapters | 501203, 501204, 501205, 501206, 501214 |
| Cap and Sleeve Kit | 501207 |
| FasTac® Flex Steerable Lead Implant Tool | 6201FAS |

Munich, MHS-CRT, 2017-12-22

Stefan Preiß