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

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 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

Digitally
Date: 202
Reason: I
Location

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

Product Service

EC Certificate
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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 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

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

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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

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