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

Product Service

EC Certificate

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 17 05 33625 016

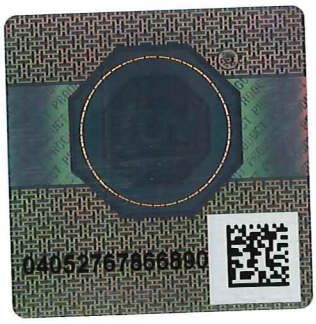
Manufacturer: **Atrotech Oy**
Hermiankatu 6-8 F
33720 Tampere
FINLAND

Product: **Implantable Neurostimulator Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report No.: 713101594

Valid from: 2017-06-01
Valid until: 2022-05-31



Date, 2017-05-31

Stefan Preiß

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

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

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No. I1 17 05 33625 016

Facility(ies):

Atrotech Oy
Hermiankatu 6-8 F, 33720 Tampere, FINLAND

Design Facility(ies):

Atrotech Oy
Hermiankatu 6-8 F, 33720 Tampere, FINLAND

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