



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
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Product Service

# EC Certificate

Production Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5

(Other devices than custom made or intended for clinical investigation)

**No. I2 039709 1117 Rev. 01**

**Manufacturer:**

**Medtronic, Inc.**

710 Medtronic Parkway  
Minneapolis, MN 55432  
USA

**Product:**

**Implantable Leads for AIMDs  
Accessories for Implantable Leads for  
AIMDs**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 5. 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 3 certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:I2 039709 1117 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:I2 039709 1117 Rev. 01)

**Report no.:**

Medtronic, Inc.  
710 Medtronic Parkway  
713194256, MIN 55432  
USA

**Valid from:**

2021-04-23

**Valid until:**

2024-05-26

**Date,**

2021-03-31



**Christoph Dicks**

Head of Certification/Notified Body