



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 11 11 39040 034

**Manufacturer:**

**Medtronic Sofamor Danek  
USA, Inc.**

1800 Pyramid Place  
Memphis, TN 38132  
USA

**EC-Representative:**

**Medtronic bv**

Earl Bakkenstraat 10  
6422 PJ Heerlen  
THE NETHERLANDS

**Product  
Category(ies):**

**Spinal, Cranial, Dental, and Orthopedic Implants,  
Sterile Spinal Implants, Sterile Synthetic  
Bone Substitutes, Sterile Instruments, Cutters,  
Retractors, Electrical Drive Systems,  
Electrosurgical Instruments, Endoscopes,  
Neurological Electrodes**

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 MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

NM1110052

**Valid from:**

2012-02-01

**Valid until:**

2015-12-18

Hans-Heiner Junker

Date, 2012-02-02



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

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**No. G1 11 11 39040 034****Facility(ies):**

Medtronic Sofamor Danek USA, Inc.  
1800 Pyramid Place, Memphis, TN 38132, USA

Medtronic Sofamor Danek USA, Inc.  
4340 Swinnea Road, Memphis TN 38118, USA

Medtronic Puerto Rico Operations, Co.  
Road 909 Km. 0.4 Bo, 00792 Barrio Mariana, Humacao, PUERTO RICO USA

Medtronic Puerto Rico Operations, Co.  
Parcela #21, Catano Industrial Park, Dr. John A. Smith Street,  
00792 Humacao, PUERTO RICO USA

Medtronic Sofamor Danek Manufacturing  
2500 Silveus Crossing, Warsaw, IN 46582, USA

Medtronic Sofamor Danek Deggendorf GmbH  
Werftstr. 17, 94469 Deggendorf, GERMANY

Medtronic Sofamor Danek Deggendorf GmbH  
Ulrichsberger Str. 17, 94469 Deggendorf, GERMANY