

EC Design Examination Certificate
EEC Directive 90/385/EEC Annex 2, Article 4
Active Implantable Medical Devices
as last amended by EC Directive 93/68/EEC

Registration No.: II 60015743 0001

Report No.: 21114148 003

Manufacturer:

Neurodan A/S
Sofiendalsvej 85
9200 Aalborg
Denmark

Manufacturing Facility:

Product:

Implantat
Active Implant

Identification:

ActiGait® Implantable Drop Foot System


Components: See Attachment

The EC design examination certificate refers to the above mentioned product. It certifies that the design documentation of the product complies with Annex 2, Article 4 of the directive. The manufacturer is subject to EC surveillance in accordance with Annex 2, Article 5 of the directive. The manufacturer is entitled to use this certificate with the manufacturer's declaration of conformity.

Date of Expiry: 24.09.2011

Notified Body

Cologne, 25.09.2006



Dipl.-Ing. I. Munkler



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: II 60015743 0001
Report No.: 21114148 003

Manufacturer: Neurodan A/S
Sofiendalsvej 85
9200 Aalborg
Denmark

Scope: Components:

Implants:

- Model 452
- Model 542
- Model 642
- Model 762
- Model 882

Patient System:

- External Unit
- Antenna Fixture
- Heel Switch, Type A
- Heel Switch, Type B
- Sock, div. Sizes and Colors
- Power Supply

Cologne, 25.09.2006


Dipl.-Ing. I. Munkler



TÜV Rheinland
Product Safety GmbH

Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: II 60015743 0001
Report No.: 21114148 003

Manufacturer: Neurodan A/S
Sofiendalsvej 85
9200 Aalborg
Denmark

Scope: Components:

Clinical Station:
- Software Version 2.x
- Service Cable

Insertion Tools:
- Point
- Tube

Nerve Sizing Tools:
- Model 452
- Model 542
- Model 642
- Model 762
- Model 882

Cologne, 25.09.2006


Dipl.-Ing. I. Munkler



APPROVAL

EC Directive 90/385/EEC Annex 2, Article 3
Active Implantable Medical Devices
Full Quality Assurance System
as last amended by EC Directive 93/68/EEC

Registration No.: HI 60015394 0001

Report No.: 21121924 002

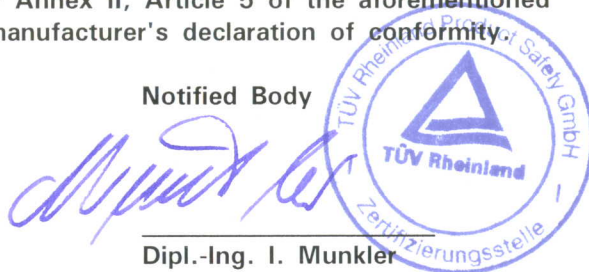
Manufacturer: Neurodan A/S
Sofiendalsvej 85
9200 Aalborg
Denmark

Scope: Design and development, production and sales
of neurostimulation devices

Date of Expiry: 17.04.2011

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity

Notified Body



Cologne, 25.09.2006

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
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