



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 05 33625 017

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



Product: **Implantable Neurostimulator Systems**

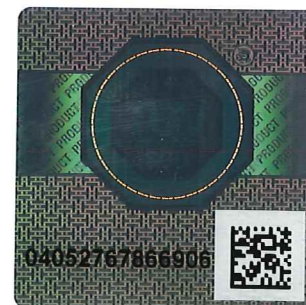
The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713101594

Valid from: 2017-05-31
Valid until: 2022-05-28

Date, 2017-05-31

Stefan Preiß



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

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No. 17 17 05 33625 017

Model(s): **Atrostim Phrenic Nerve Stimulator
(Atrostim PNS)
(see attachment)**

Parameters: *./.*

Facility(ies): Atrotech Oy
Hermiankatu 6-8 F, 33720 Tampere, FINLAND

**Design
Facility(ies):** Atrotech Oy
Hermiankatu 6-8 F, 33720 Tampere, FINLAND



Attachment for Certificate no I7 17 05 33625 017
dated 2017-05-31

Products: Implantable Neurostimulator Systems

**Atrostim Phrenic Nerve Stimulator
Atrostim PNS Version 2.0**

Test Report No.: 713001874

Implantable components:

Model:	Model no:
Implantable Stimulator	RX 44-27-2 CL
Electrode for adult patient	TF 4A
Electrode for paediatric patient	TF 4BR
Extension Lead for paediatric patient	EL 1.5, 3, 4
Shield Cap	SC

External components:

Model:	Model no:
Stimulus Controller	PX 244 L
Programming Module	PHS 240+
Module Cable	MC 52
Energy Transfer Coils	TCL 27
Energy Transfer Cables	PCL 80

Munich, MHS-CRT, 2017-05-31

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Stefan Preiß
Certification Medical Technology