Declaration of Conformity

Finetech Medical Ltd
13 Tewin Court
Welwyn Garden City
Hertfordshire
AL7 1AU
United Kingdom

We, Finetech Medical Ltd.,

declare that the **Finetech-Brindley** *Sacral Anterior Root Stimulator* (an implantable nerve stimulator whose main purpose is the stimulation of bladder, bowel and erection functions) is an active implantable medical device and conforms with the requirements of:

European Council Directive 90/385/EEC concerning Active Implantable Medical Devices.

This declaration covers the implants; associated external control devices, repair kits and sterile medical adhesive.

The **Finetech-Brindley** is treated with the same degree of risk as a Class 3 device, and is assessed under the Active Implantable Medical Device Directive; AIMD 90/385/EEC. Conformity assessments have been carried out by BSI (*Notified Body 0086; Medical Device Certification, BSI Product Services, Maylands Avenue, Hemel Hempstead, HP2 4SQ United Kingdom*) according to the procedures laid down in annex 3 and annex 5 of the directive.

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Approved By:	Date:
John Spensley	22 Oct 07

Document History				
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01/05/1996	001	New Document	n/a	D Keeling
08/12/2003	002	Electronic update	n/a	P Clarke
18/07/2007	003	Conformity assessment update, new template	397	J Spensley