



**APPROVAL**  
**EC Directive 93/42/EEC Annex II, Article 3**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60019519 0001

**Report No.:** 30792400 001

**Manufacturer:** TechDevice Corporation  
650 Pleasant St.  
Watertown, MA 02472  
USA

**Scope:** Design and Development and Manufacture of Guidewires for Use  
in the Alimentary Track or the Peripheral Vascular System

Replaces Approval, Registration No.: HD 60013911 0001

**Date of Expiry:** 19.12.2012

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, 01.04.2008

*B. Ludovico*  
B. Ludovico

**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.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE