

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

Registration No.: HD 60024117 0001

Report No.: 30892219 002

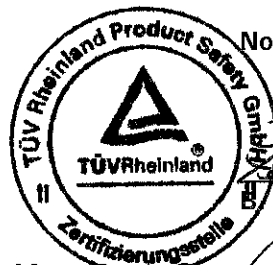
Manufacturer: Sandel Medical Industries, LLC  
19736 Dearborn Street  
Chatsworth CA 91311  
USA

Scope: Design/Development and Manufacture of Safety Scalpels

Date of Expiry: 03.03.2014

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.

Cologne, 04.03.2009



Notified Body

*Ludovico*  
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.

