TÜVRheinland®

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.

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Cologne, 04.03.2009

ppa. 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