

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60024118 0001

Report No.: 30892219 002

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

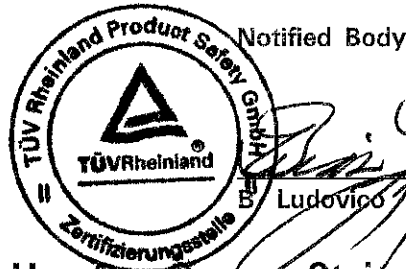
Scope: Aspects of Manufacture Concerned with Securing and
Maintaining Sterile Conditions.

Products: see attachment

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 V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 04.03.2009



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

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

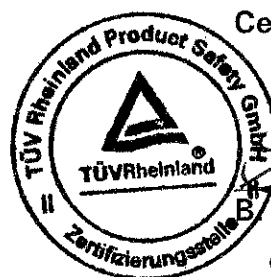
Attachment to
Registration No.: DD 60024118 0001
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Manufacturer: Sandel Medical Industries, LLC
19736 Dearborn Street
Chatsworth CA 91311
USA

Scope: Products:

- Scalpel Handle
- Skin Marker

Cologne, 04.03.2009



Certification Body

[Signature]
Ludovico