

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

Registration No.: DD 60026258 0001

Report No.: 28207435 002

Manufacturer: S.C. VELFINA S.A.
Iezer Street No. 7
115100 Campulung-Arges
Romania

Scope: Aspects of manufacture concerned with securing and
maintaining sterile conditions

(see attachment for products and additional sites included)

Date of Expiry: 29.07.2014

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, 27.10.2009



Notified Body

Dr. G. Viola
Dr. G. Viola

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 60026258 0001
Report No.: 28207435 002

Manufacturer: S.C. VELFINA S.A.
Iezer Street No. 7
115100 Campulung-Arges
Romania

Scope: Products: see attachment

- Sterile gauze compresses
- Sterile plasters/strips
- Sterile surgical drapes
- Sterile surgical drapes kits
- Sterile surgical gowns
- Sterile non-woven compresses

Cologne, 27.10.2009

Certification Body



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Manufacturer: S.C. VELFINA S.A.
Iezer Street No. 7
115100 Campulung-Arges
Romania

Scope: Site included:

S.C. VELFINA S.A.
17 Ticaloiu Street
115100 Campulung

Design/Development and manufacture of non-active
Medical Devices

Cologne, 27.10.2009

