

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

Registration No.: HD 60026259 0001

Report No.: 28207435 002

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

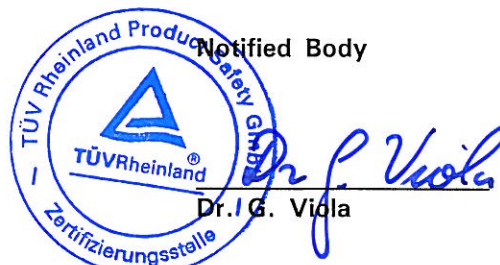
Scope: Design/Development and Manufacture of
non-active Medical Devices

(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 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, 27.10.2009



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

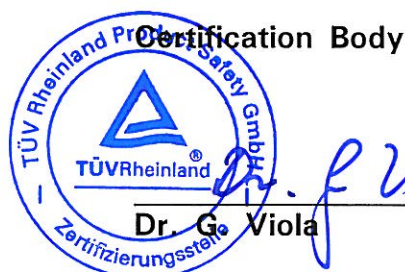
Attachment to
Registration No.: HD 60026259 0001
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Manufacturer: S.C. VELFINA S.A.
Iezer Street No. 7
115100 Campulung-Arges
Romania

Scope: Products:

- Sterile gauze compresses
- Sterile paraffine impregnated compresses
- Sterile polyurethane dressings
- Sterile polyurethane dressings with hydrocolloid
- Sterile polyurethane films
- Sterile hydrocolloid dressings
- Sterile hydrogel solutions/hydrogel impregnated compresses
- Sterile cleaning/irrigation solutions
- Sterile hydrogels for wound debridement

Cologne, 27.10.2009



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

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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 Device

Cologne, 27.10.2009

