

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

Registration No.: HD 60025521 0001

Report No.: 28207480 002

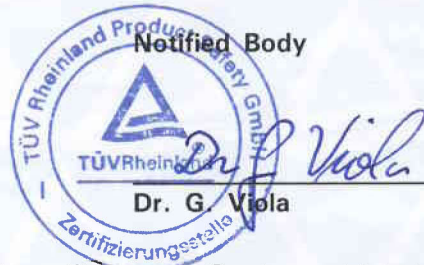
**Manufacturer:** KANSUK Laboratuari  
Sanayi ve Ticaret AS  
Eski Londra Asfalti,  
Besyol mah. No. 4  
34620 Sefaköy, Istanbul  
Turkey

**Scope:** Design/development and manufacturing of blood bags  
and blood transfusion sets  
  
Replaces approval, registration no.: HD 60008399 0001

**Date of Expiry:** 09.06.2014

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, 10.06.2009



**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