



## APPROVAL

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

Registration No.: HD 60017109 0001

Report No.: 30690450 001

**Manufacturer:** Terumo Medical Corporation  
950 Elkton Boulevard  
Elkton, Maryland 21921  
USA

**Scope:** Design, development and manufacturing of  
disposable medical devices

Products: see attachment

Replaces Approval, Registration No.: HD 2111523 01

**Date of Expiry:** 08.02.2012

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.



Notified Body

Cologne, 09.02.2007

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.

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

Attachment to  
Registration No.: HD 60017109 0001  
Report No.: 30690450 001

Manufacturer: Terumo Medical Corporation  
950 Elkton Boulevard  
Elkton, Maryland 21921  
USA

Scope: Products:  
- Syringes  
- Needles  
- Infusion Sets  
- Intravenous Catheters  
- Introducer Kits  
- Injection Plugs  
- Guiding Sheath