

**APPROVAL**  
**EC Directive 98/79/EC Annex IV, Article 3**  
**Full Quality Assurance System**  
**In vitro diagnostic medical devices**

**Registration No.:** HL 60027312 0001

**Report No.:** 21143523 002

**Manufacturer:** Fujirebio Diagnostics AB  
Elof Lindälvs gata 13  
SE-414 55 Göteborg  
Sweden

**Scope:** Design and development, manufacture and final inspection of reagents and reagent products for determining the tumoral marker PSA


**Date of Expiry:** 18.10.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 19.10.2009



Notified Body

  
Dr. H. Lüdemann

**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.



The CE marking may be used if all relevant and effective EC Directives are complied with.

