



QUALITY SYSTEM

CERTIFICATE

Directive 98/79/EC

Manufacturer: Fujirebio Diagnostics AB
Majnabbe Terminal
SE-414 55 Gothenburg
Sweden

Coverage of Certificate: Design, manufacture and final inspection

Product category: Reagents and reagent products for
determining tumoral marker PSA

Valid until: 16th October, 2009

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. This Certificate is based on decision no. VTT-C-1028-02-1085-263-06-P0.

Tampere, 16th October, 2006

Kaarle Kylmä



Markku Helminen

Certificate no.
VTT-C-1028-02-1085-263-06

Notified Body no. 0537:
VTT Technical Research Centre of Finland
P.O. Box 1300 (Tekniikankatu 1)
FI-33101 TAMPERE
Tel.+358 20 722 111



QUALITY SYSTEM

CERTIFICATE

ISO 13485:2003

Fujirebio Diagnostics AB

Majnabbe Terminal, SE-414 55 Gothenburg
SWEDEN

VTT has assessed the company's quality system and
found that it meets the requirements of ISO 13485:2003.

This certificate covers the following functions:

**Development, production, marketing and sales of reagents, and
complete reagent packages (kits) for in-vitro diagnostics**

Issued:

16th October, 2006

Valid until:

16th October, 2009

First issued:

14th October, 2003

Kaarle Kylmä
Service Manager
VTT

Markku Helminen
Lead Assessor
VTT



Certification body:

VTT

Product Approval and Certification

P.O.Box 1000, FI-02044 VTT

Finland

Tel.+358 20 722 111

Certificate no:

VTT-C-1029-60-7009-B-06