

# UL International (UK) Ltd

An affiliate of Underwriters Laboratories Inc.

## EC Certificate - Full Quality Assurance System Approval Certificate

(Annex IV, section 3 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

### Manufacturer

Mediwatch (UK) Ltd  
Lumonics House  
Valley Drive  
Rugby CV21 1TQ  
United Kingdom

### Authorised Representative

Not applicable

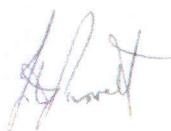
**Scope of Certificate:** Design and manufacture of immunoassay reagent cassette and cassette reader for quantitative determination of total Prostate Specific Antigen

**Device Classifications:** Annex II, List B

**Device descriptions:** PSAwatch quantitative immunoassay reagent cassette and cassette reader.

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Certificate issued by:



**Certification Manager**  
For UL International (UK) Ltd

UL International (UK) Ltd  
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Certificate no: 504  
Original certificate: 20 February 2007  
Current certificate: 14 September 2010  
Attachments: N/A  
Certificate expiry: 12 November 2012

Notified Body No.

**0843**