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

Qualigen Inc
2042 Corte del Nogal
Carlsbad CA 92009
USA

Authorised Representative

Medical Device Safety Service (MDSS)
Burckhardtstr. 1
30163 Hannover
Germany

Scope of Certificate:	The design and manufacture of in vitro diagnostic devices for quantitative detection of Free and Total PSA by immunoassay
Device Classifications:	Annex II List B
Device descriptions:	FastPack® immunoassay, calibrators and controls

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
Wonersh House
The Guildway
Old Portsmouth Road
Guildford, Surrey GU3 1LR
United Kingdom
+44 (0)1483 302130

Certificate no:	351
Original certificate:	7 April 2004
Current certificate:	15 June 2009
Attachments:	None
Certificate expiry:	15 June 2012

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