

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

ProBioQual
9 Rue Professeur Florence
69003
Lyon
France

Authorised Representative

Not Applicable

Scope of Certificate: Supply of Trisomy 21 multi-constituent quality controls for use with clinical chemistry immunoassay systems

Device Classifications: Annex II, List B

Device descriptions: Serum S

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: 617
Original certificate: 27 January 2010
Current certificate: 27 January 2010
Certificate expiry: 20 April 2011

