EC CERTIFICATE

ProBioQual

7 Rue Antoine Lumière
69008 LYON
FRANCE

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

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

Device Classification:
Annex II, list B

Device Descriptions / Model:
CIQ – MSMPE – Sérum S:

File Number	A16603	Cycle Start Date	21 April 2017
Certificate No.	617.171005	Effective Date	05 October 2017
		Expiry Date	18 August 2020

Authorised by

C.H. Tonkin
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report Project No 11852153, 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 Council 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 and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with (0) attachments listing model numbers and (0) addendums listing additional locations covered by this certificate.

Notified Body

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