

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

Bioclone Australia Pty Limited
71-73 Railway Parade
Marrickville
Sydney
NSW 2204
Australia

Authorised Representative

Hitachi Chemical Diagnostics Inc.
Hitachi Europe Ltd.
Whitebrook Park
Lower Cookham Road
Maidenhead
Berkshire SL6 8YA
United Kingdom

Scope of Certificate: The design, manufacture and distribution of in vitro diagnostic kits and reagents for detection of species-specific antibodies to Chlamydia in human serum and quantitative measurement of L-phenylalanine in the screening of human neonatal blood spots.

Device Classifications: Annex II, List B

Device descriptions: Please refer to attachment 1

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

Certificate no: 347
Original certificate: 22 March 2004
Current certificate: 22 July 2010
Certificate expiry: 22 March 2013

Notified Body No.

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