



APPROVAL OF CONFORMITY CERTIFICATE

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**Biochrom Ltd
22, Cambridge Science Park, Milton Road
Cambridge, Cambridgeshire, CB4 0FJ
United Kingdom**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for List A products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule and continued satisfactory compliance with the requirements for verification of manufactured product.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0890333/C
Original Approval: 25 May 2004
Current Certificate: 1 November 2009
Certificate Expiry: 31 October 2012
LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



**APPROVAL OF CONFORMITY CERTIFICATE
CERTIFICATE LRQ 0890333/C SCHEDULE**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

**Biochrom Ltd
22, Cambridge Science Park, Milton Road
Cambridge, Cambridgeshire, CB4 0FJ
United Kingdom**

Annex II List B Products

Reagent kit for the diagnosis of Phenylketonuria:-

Ultra Physiological Fluid Chemical Kit Car Ref 80-2117-77

Lithium Buffer A	Cat. Ref. 80-2038-15
Lithium Buffer B	Cat. Ref. 80-2038-16
Lithium Buffer CII	Cat. Ref. 80-2099-83
Lithium Buffer DII	Cat. Ref. 80-2097-18
Lithium Buffer Ph 3.55	Cat. Ref. 80-2037-69
Lithium Hydroxide Solution	Cat. Ref. 80-2038-20

Ultra Ninhydrin Kit Cat. Ref. 80-2118-30 (Comprising Ultra ninhydrin solution 80-2117-64 and Ultrasolve Plus 80-2118-65)

Schedule Issue: 1

Date of Schedule Issue: 1 November 2009

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