

## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

**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  
1020 Cambourne Business Park,  
Cambourne, Cambridge,  
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.

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 2018  
Certificate Expiry: 30 April 2019  
LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

**EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM  
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  
1020 Cambourne Business Park,  
Cambourne, Cambridge,  
United Kingdom**

**Annex II List B Products**

Ultra Physiological Fluid Kit	Cat. Ref. 80-2117-77
Ultra Physiological Routine Kit	Cat. Ref. 80-6000-06
Biochrom Lithium Buffer Start-up Kit	Cat. Ref. 80-6000-16
Biochrom Lithium Buffer Routine Kit	Cat. Ref. 80-6000-17
Containing:	
• Lithium Buffer 1	Cat. Ref. 80-2038-15
• Lithium Buffer 2	Cat. Ref. 80-2038-16
• Lithium Buffer 3	Cat. Ref. 80-2099-83
• Lithium Buffer 4	Cat. Ref. 80-2097-18
• Lithium Buffer 5	Cat. Ref. 80-2037-69
• Lithium Regeneration Buffer 6	Cat. Ref. 80-2038-20
Ultra Ninhydrin Kit 2L	Cat Ref: 80-2118-30
Ultra Ninhydrin Kit 8L	Cat Ref: 80-2117-76
Both containing:	
• Ultra Ninhydrin Solution	Cat. Ref. 80-2117-64
• Ultrosolve Plus	Cat. Ref. 80-2117-65
EZ Nin Reagent Kit 2L	Cat. Ref. 80-6000-13
EZ Nin Reagent Kit 4L	Cat. Ref. 80-6000-14
EZ Nin Reagent Kit 8L	Cat. Ref. 80-6000-15
Containing:	
• EZ Nin Reagent	Cat. Ref. 80-6000-12

Schedule Issue: 01

Date of Schedule Issue: 1 November 2018

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