

# EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

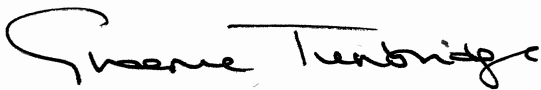
**No.** CE 735267  
**Issued To:** **Biochrom Ltd**  
**Unit 7, Enterprise Zone**  
**3970 Cambridge Research Park**  
**Beach Drive**  
**Waterbeach**  
**Cambridge**  
**CB25 9PE**  
**United Kingdom**

In respect of:

**Design and manufacture of IVD reagents and buffers for the diagnosis of the metabolic disease phenylketonuria.**

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2020-10-15**

Date: **2022-04-26**

Expiry Date: **2025-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 735267

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Number	Device Name	Intended per IFU
<b>Annex II List B</b>		
IVD0304	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 Ultra Ninhydrin Kit 2L Cat. Ref. 80-2118-30 Ultra Ninhydrin Kit 8L Cat. Ref. 80-2117-76 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	Quantitative analysis of the amino acid phenylalanine in de-proteinised blood plasma as an aid in the diagnosis and monitoring of the metabolic disease Phenylketonuria.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**United Kingdom**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	<b>EU Representative</b>
Melford Laboratories Ltd. Bildeston Road Chelsworth Ipswich Suffolk IP7 7LE UK	<b>Manufacture</b>

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# EC Certificate - Full Quality Assurance Certificate History

**Certificate No:** CE 735267  
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Date	Reference Number	Action
15 October 2020	3279743	First Issue.
01 June 2021	3403636	Manufacturer address changed; EU Representative details added.
28 October 2021	3511943	Renewal.
Current	3658532	Amended – Change to the content of the Device Table to remove references to kit components. Change of IVDD expiry date according to Regulation (EU) 2022/112.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

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