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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Supplementary Information to CE 735267

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United Kingdom

Number	Device Name	Intended per IFU
Annex II List 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.

First Issued: **2020-10-15** Date: **2022-04-26** Expiry Date: **2025-05-26**

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By Royal Charter

EC Certificate - Full Quality Assurance

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

List of Significant Subcontractors

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

Certificate No:	**CE 735267**
Date:	**2022-04-26**
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Subcontractor:	**Service(s) supplied**
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	**EU Representative**
Melford Laboratories Ltd. Bildeston Road Chelsworth Ipswich Suffolk IP7 7LE UK	**Manufacture**

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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.