Declaration of Conformity

Manufacturer: Biochrom Ltd[1]
Address: Unit 7, Enterprise Zone, 3970 Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, CB25 9PE UK

We herewith declare, under our sole responsibility, that the following Amino Acid analyser chemicals and reagent buffers:

Products[2]			**Catalogue Reference**
Ultra Physiological Fluid kit[3]			80-2117-77
Ultra Physiological Routine Kit			80-6000-06
Lithium Buffer Start-up Kit[3]			80-6000-16
Lithium Buffer Routine Kit			80-6000-17
	Kits contain	Lithium Buffer 1	80-2038-15
		Lithium Buffer 2	80-2038-16
		Lithium Buffer 3	80-2099-83
		Lithium Buffer 4	80-2097-18
		Lithium Buffer 5	80-2037-69
		Lithium Regeneration Buffer 6	80-2038-20
Ultra Ninhydrin Reagent Kit, 2L			80-2118-30
Ultra Ninhydrin Reagent Kit, 8L			80-2117-76
	Kits contain	Ultra Ninhydrin Solution	80-2117-64
		Ultrosolve Plus	80-2117-65
EZ Nin Reagent Kit, 2L			80-6000-13
EZ Nin Reagent Kit, 4L			80-6000-14
EZ Nin Reagent Kit, 8L			80-6000-15
	Kits contain	EZ Nin Reagent	80-6000-12

Are in conformity of the following applicable European Union harmonisation legislation[2]:
98/79/EC In Vitro medical devices directive[4]

Are in conformity of the following applicable statutory UK requirements[5]:
SI 2002 No. 618 Medical Devices Regulation 2002

EU Notified Body: BSI, Say Building, John M. Keynesplien 9, 1066 EP, Amsterdam, The Netherlands
BSI Group, The Netherlands, BV
Notified body number: 2797
Certificate number: CE 735267

EU Authorised Representative:
MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany

[1]Biochrom Ltd hold ISO 9001:2015 and ISO13485:2016 certificates for its Quality Management System. The management system is also certified as conforming to MDSAP in accordance with Canadian Medical Device Regulations – Part 1- SOR 98/282 PMD Act and United States FDA regulations 21 CFR 803, 21 CFR 806, 21 CFR 807 –subparts A to D and 21 CFR 820
[2]Conformance is declared for the use of the above buffers and kits in the diagnosis of the metabolic disease Phenylketonuria
[3]Products 80-2117-77 and 80-6000-16 additionally include 80-2038-10 Lithium Loading Buffer
[4]IVD Product classified in accordance Annex II List B; reagents and reagent products for diagnosis and conforming to IVD Annex I and IV, verified by notified body
[5]As amended by UK SI 2019 No. 696

I, the undersigned, hereby declare that the product specified are in conformity with the relevant harmonised Union legislation and applicable UK statutory Instruments. Signed for and on behalf of Biochrom Ltd at Waterbeach, Cambs,UK

biochrom
a division of
Harvard Bioscience, Inc.

Signed:

Heather Tudor
Quality and Regulatory Affairs Manager,
Biochrom

Date:
27 April 2022