biochrom

CE

Declaration of Conformity

Name of Manufacturer:	Biochrom Ltd.
Address of Manufacturer:	Unit 7, Enterprise Zone 3970 Cambridge Research Park Beach Drive, Waterbeach Cambridge, United Kingdom CB25 9PE
SRN:	GB-MF-00025158

Product Details:

Model	Product Name and Description
80-6000-50	Bio 30+ System Physio Accel
80-6000-51	Bio 30+ Physio Accelerated
80-6000-52	Bio 30+ Physio Accel W/O A/S
80-6000-53	Bio 30+ System Physio HP
80-6000-53EZ	Bio 30+ Sys Physio HP EZ Nin
80-6000-54	Bio 30+ Physio High Performance
80-6000-55	Bio 30+ Physio W/O A/S HP
80-6000-56	Bio 30+ System Physio HR
80-6000-57	Bio 30+ Physiological HR
80-6000-58	Bio30+ Physio W/O A/S HR

Intended use	The Biochrom Bio 30+ Amino Acid Analyser is a fully automated laboratory instrument intended as an aid to the diagnosis of phenylketonuria by trained professionals. The Biochrom Bio 30+ Amino Acid Analyser is designed to provide quantitative analysis of phenylalanine and tyrosine present in physiological samples using ion-exchange chromatography in combination with post-column derivatization using ninhydrin. Physiological samples of human origin limited to de-proteinised blood plasma samples. The Biochrom Bio 30+ Amino Acid Analyser is not intended to be used as a standalone diagnostic test for any patient condition or disease and is for in vitro use only.
Risk Class of Medical Device as per Annex VIII of Regulation of EU IVDR 2017/746:	Class A – Rule 5 (a)
Conformity Assessment Route:	N/A – NB conformity assessment not required since device is a non-sterile Class A device, per article 48 (10) of Regulation of EU IVDR 2017/746.
Basic UDI-DI:	50563368AAAIVDSC0013Q
EU Authorised representative:	Medical Device Safety Service (MDSS) GmbH Schiffgraben 41, 30175, Hannover, Germany
CH Authorised representative:	Medical Device Safety Service (MDSS) CH GmbH Laurenzenvorstadt 61, 5000 Aarau, Switzerland
Regulation:	EU IVDR 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Standards & Common specifications: See Attachment 1

We Biochrom Ltd declare under our sole responsibility that the in-vitro diagnostic devices listed above comply with the relevant provisions of EU IVDR 2017/746 and the above-mentioned standards.

Name: Heather Tudor

Designation: Quality and Regulatory Affairs Manager, Biochrom

Sign: 

Place: Cambridge, United Kingdom

Date: 09 March 2023

biochrom

CE

Attachment 1: List of Standards and Common Specifications

Document Reference	Document Title
EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
IEC 62366-1:2015	Medical Devices-Part 1: Applicability of Usability Engineering to Medical Devices
IEC 61010 series	Safety requirements for electrical equipment for measurement, control, and laboratory use
IEC 62304: 2006+AMD1 :2015	Medical device software - Software life cycle processes
IEC 61000 series	Standards for Power Supplies
EN ISO 15223-1	Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied- Part 1: General Requirements
EN ISO 18113 Series	Invitro Diagnostic Medical Devices-Information supplied by the manufacturer (labelling)
ISO 20916:2019	Clinical performance studies using specimens from human subjects
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
MDCG 2022-2	Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)
Regulation 1272_2008	Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures (CLP)
GHTF SG5/N6: 2012	Clinical evidence for IVDs: Key definitions and concepts
GHTF SG5/N7:2012	Clinical evidence for IVDs: Scientific Validity Determination and Performance Evaluation
GHTF SG5/N8:2012	Clinical evidence for IVDs-Clinical Performance Studies
RoHS Directive 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment.
WEEE DIRECTIVE 2012/19/EU	Waste electrical and electronic equipment.