UKCA Declaration of Conformity

This is a declaration made in accordance with the requirements of the UK Medical Devices Regulations 2002 (as amended) (UK MDR 2002).

This Declaration of Conformity is issued under the sole responsibility of Entia Ltd.

Product Identification	
General Product Name	Entia Liberty®
Product Codes	20-100-01 - Liberty Analyser 20-200-01 - Liberty Cuvette (Box of 20 cuvettes) 20-300-01 - Liberty Cuvette (Box of 5 cuvettes)
Product Description	The Entia Liberty® ("Liberty") is intended for use in the quantitative determination of neutrophils, haemoglobin, platelets and total white blood cells from capillary blood. Liberty is for in-vitro diagnostic use only and is intended for remote monitoring of blood counts by healthcare professionals for a patient undergoing systemic anti-cancer treatment. Liberty is used for self-testing in the home environment. The Entia Liberty consists of a connected blood count analyser (Liberty Analyser) and a container that captures a blood sample (Liberty Cuvette). The Entia Liberty is suitable for use by patients aged 18+ that are receiving therapy and who may have potentially compromised immune systems. The Entia Liberty is not intended to replace professional medical care, and is not suitable for patients who have haematological cancers.
GMDN Code	

GMDN Code	Definition	Entia Liberty
35476	Haematological cell analyser IVD - An electrically-powered automated or semi-automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology which may include cell lysis, electrical impedance, conductivity and/or light scatter to measure and/or calculate white cell, red cell and platelet parameters and indices in	Liberty Analyser

		a clinical specimen.	
	61032	Laboratory analyser cuvette IVD, single-use - A small-volume, rectangular column designed to contain a clinical specimen, reagent, or other material for in vitro diagnostic testing procedures performed by a laboratory analyser. It is transparent to allow light to travel through the contained material and is typically made of plastic, glass or quartz with a flat base and an open top. This is a single-use device.	Liberty Cuvette

Legal Manufacturer	
Company Name	Entia Ltd
Address	52 Princes Gate, Exhibition Road, London, SW7 2PG, UK

Registration Information	
Notified Body	BSI Assurance UK Ltd
Notified Body ID Number	0086
UKCA Certificate Number	UKCA 776723
UKCA Certificate First Issue Date	2023-11-03
Address	Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP
Country	United Kingdom
Phone Number	+44 (0)845 080 9000
Email	MedicalDevices@bsigroup.com
Website	www.bsigroup.com

Conformity Assessment	
Device Classification according to Annex II (as modified by Part III of	Self-testing IVDs excluding those in Annex II

Schedule 2A to the UK MDR 2002)	
Route to Compliance	UK MDR 2002 via Annex IV of Council Directive 98/79/EC
Quality System Certification	ISO 13485:2016
	Certificate Number: MD 653068
	Issued by: BSI

Standards Applied	
Standard reference	**Standard title**
ISO 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
BS EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
BS EN ISO 13485:2016+A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2019 + A11:2021	Medical devices - Application of risk management to medical devices
ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-4:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)
EN ISO 18113-5:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
IEC 61010-1:2010/AMD1:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006+A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices

EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices

A complete reference of standards and guidances used and complied with is held by Entia Ltd

Declaration of Conformity to EU RoHS Directive

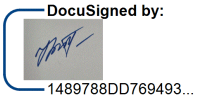
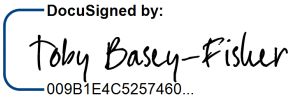
From 13/11/2019, products manufactured by Entia Ltd are in compliance with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 - amended 22 July 2019 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Declaration of Conformity to GB RoHS Regulations

From 01/01/2021, products manufactured by Entia Ltd are in compliance with Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 amended 1 January 2021 (Brexit) and 31 October 2022.

This declaration of conformity is issued under the sole responsibility of Entia Ltd. Specifically, products manufactured do not contain the substances in the table below in concentrations greater than the listed maximum value.

Substance	Maximum Value
Lead (Pb)	0.1%
Mercury (Hg)	0.1%
Cadmium (Cd)	0.01%
Hexavalent Chromium (Cr6+)	0.1%
Polybrominated biphenyls (PBB)	0.1%
Polybrominated diphenyl ethers (PBDE)	0.1%
Bis (2-ethylhexyl) phthalate (DEHP)	0.1%
Benzyl butyl phthalate (BPP)	0.1%
Dibutyl phthalate (DBP)	0.1%
Diisobutyl phthalate (DIBP) (GB RoHS)	0.1%

Name:	Nataliya Noreika	**Function:**	Head of RA/QA
Date:	21/11/2023	**Place of issue:**	Entia Ltd, 52 Princes Gate, Exhibition Road, London, SW7 2PG, UK
Signature:	DocuSigned by:  1489788DD769493...		
Name:	Toby Basey-Fisher	**Function:**	CEO
Date:	21/11/2023	**Place of issue:**	Entia Ltd, 52 Princes Gate, Exhibition Road, London, SW7 2PG, UK
Signature:	DocuSigned by:  009B1E4C5257460...		