



UKCA Certificate - Full Quality Assurance System

Part IV of The Medical Devices Regulations 2002, Annex IV excluding Sections 4 and 6 [as modified by Part 3 of Schedule 2A to The Medical Devices Regulations 2002]

No. Issued To:

UKCA 776723

Entia Ltd 52 Princes Gate Exhibition Road London SW7 2PG United Kingdom

In respect of:

Design and Manufacture of Self-test Optical IVDs for Blood Constituent Analysis.

On the basis of our examination under the requirements of Part IV of The Medical Devices Regulations 2002, Annex IV excluding Sections 4 and 6 [as modified by Part 3 of Schedule 2A to The Medical Devices Regulations 2002], the quality system was found to meet the requirements of this regulation. For the placing on the market of List A devices covered by this certificate, a UKCA Design-Examination Certificate according to Annex IV Section 4 (modified as described above) and a letter releasing each batch according to Annex IV Section 6 (modified as described above) are required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: 2023-11-03

Date: 2023-11-03

Expiry Date: 2028-11-02

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000 Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK. A member of BSI Group of Companies.





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Supplementary Information to UKCA 776723

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Device Code	Device Name	Intended purpose per IFU
Non-Annex II Self-test		
IVD0402	Liberty	The Entia Liberty® ("Liberty") device 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 systematic anti-cancer treatment. Liberty is used for self-testing in the home environment.

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Page 2 of 2

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UKCA Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number		Action
Current	3736543	Issued	1912 Love Excert



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Page 1 of 1