By Royal Charter

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. **UKCA 776723**

Issued To: **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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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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UKCA Certificate - Full Quality Assurance System Certificate History

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Date: **2023-11-03**
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Date	Reference Number	Action
Current	3736543	Issued

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