EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 752850**

Issued To: **Icle Test Limited**
Pure Offices
Plato Close
Tachbrook Park
Warwick
CV34 6WE
United Kingdom

In respect of:

Design and manufacture of colorimetric IVD tests for the early detection of blood in urine self-test.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-09-03** Date: **2021-09-03** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 752850

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Device code	Device name	Intended purpose per IFU
Non-Annex II Self-test		
IVD 0401	Icle Test	Icle Test is a DIY home test for In Vitro Diagnostic use only to identify blood in urine. Test result may provide information regarding the status of kidney infections, kidney stones, urethritis, cystitis, enlarged prostate gland, prostate /bladder / kidney cancers.

First Issued: **2021-09-03** Date: **2021-09-03** Expiry Date: **2024-05-26**

By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 752850**
Date:	**2021-09-03**
Issued To:	**Icle Test Limited** **Pure Offices** **Plato Close** **Tachbrook Park** **Warwick** **CV34 6WE** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Advena Limited Tower Business Centre 2nd Floor, Tower Street Swatar BKR 4013 Malta	**EU Representative**
DFI Co Ltd 388-25, Gomo-ro, Jillye-myeon Gimhae-si Gyeongsangnam-do Korea	**Manufacture**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 752850**
Date: **2021-09-03**
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Date	Reference Number	Action
Current	3481532	First issue.