EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV Section 4

No. **CE 675199**

Issued To: **Atomo Diagnostics Ltd**
Level 1
3-5 George Street
Leichhardt
New South Wales
2040
Australia

In respect of:

Atomo HIV Self Test

on the basis of our examination of the design dossier relating to the device under the requirements of Council Directive 98/79/EC, Annex IV Section 4, the design of the device conforms to the requirements of 98/79/EC.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2017-10-04** Date: **2022-05-16** Expiry Date: **2025-05-26**

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Catalogue number	Device Name	Model Type	Intended Purpose per IFU	Classification
ARST001-02	Atomo HIV Self Test	N/A	The Atomo HIV Self Test is a single-use, immunochromatographic, rapid in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in whole blood. The Atomo HIV Self Test is intended to be used by untrained lay users in a private setting as a self test to aid in the diagnosis of infection with HIV-1 and HIV-2 from samples of fresh, whole blood obtained through a finger stick blood collection technique. The device requires a sample size of 10uL. The test result is qualitative ("your test is positive" or "your test is negative") and not for screening blood donors. The test incorporates an in-built sample control mechanism to ensure that the test has been performed correctly; this control line only appears on the test device if the correct test procedure has been followed.	Annex II list A

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Certificate History

Date	Reference Number	Action
04 October 2017	8748000	First issue.
20 February 2019	85515928	Traceable to NB 0086.
28 June 2019	9737009	Change to quality control testing and product code update.
25 February 2020	3106935	Update to IFU and batch release testing
19 March 2021	8515928	Re-instatement after suspension. Suspension Period: 2021/03/02 until the stated re-issue date.
07 June 2021	3405361	Change to Manufacturer's name; update to IFU for minor clarifications, update of product label format.
Current	3622201	Amended – Change of manufacturer address. Reissued – Certificate renewal.

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By Royal Charter

Supplementary Information to CE 675199 - Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3

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Australia

Date: 06 July 2023

Changes Approved:

Date	Reference Number	Action
06 July 2023	3896330	Supplemented – addition of Newfoundland HIV Self Test device, catalogue numbers NFLD001-01 and NFLD001-02 branding.

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6 July 2023

Atomo Diagnostics Ltd
Level 1
3-5 George Street
Leichhardt
New South Wales
2040
Australia

To whom it may concern,

The transitional provisions specified in IVDR Article 110(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under IVDR Article 110(3) and as per the guidance provided in MDCG 2022-6. The related IVDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 675199	98/79/EC Annex IV Section 4	3896330	Addition of new brand Newfoundland HIV Self Test catalogue numbers NFLD001-01 and NFLD001-02.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices