

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

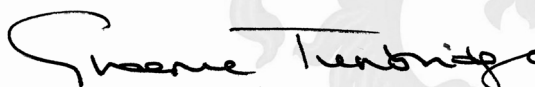
Holds Certificate Number:

MD 637069

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development and manufacture of Lateral Flow based immunoassay IVD devices and components for the detection of infectious diseases. Automated filling/labelling of buffer bottles and secondary packaging - final kit assembly.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2015-07-16

Latest Revision Date: 2022-05-04

Effective Date: 2021-07-30

Expiry Date: 2024-07-31

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 637069**

Location	Registered Activities
Atomo Diagnostics Ltd Level 1 3-5 George Street Leichhardt New South Wales 2040 Australia	The design, development and manufacture of Lateral Flow based immunoassay IVD devices and components for the detection of infectious diseases.
Atomo Diagnostics Pty Ltd 12 Waterstone Business Park 61 Capricorn Drive, Capricorn Park Muizenberg 7945 South Africa	Automated filling/labelling of buffer bottles. Secondary packaging - final kit assembly.



Original Registration Date: 2015-07-16

Latest Revision Date: 2022-05-04

Effective Date: 2021-07-30

Expiry Date: 2024-07-31

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.