

Certified for Diagnostics

Atom Scientific has a pro-active commitment to offering our customers market leading high quality validated products compliant to all relevant UK and Global Standards.

As you may be aware in May 2022 the IVD regulations were replaced with the new IVDR regulations, and since May 2022 Atom Scientifics products are fully IVDR complaint.

In addition to IVDR, all products remain CE marked in our global markets, however post-brexit the UK has adopted the UKCA mark to replace the CE mark, which all of our products are compliant with.

The IVDR regulations **require** any product that is used in a Medical or Diagnostic application to be registered under IVDR.

The ultimate aim of this change is to increase quality and consistency of diagnostic products as well as ensuring full traceability through the supply chain for all components.

It is important to note that any product not registered under IVDR should only be used in research applications, and should not be used in diagnostic applications as recommended by UKAS.

Atom Scientific is one of the few companies that has achieved IVDR compliance, alongside upgrading our Quality Management System to be ISO13485 compliant.

So to conclude I am really pleased to introduce you to our range of Special Stains & Stain Kits offering you pre-validated, Certified for Diagnostic Use and supported by my dedicated Technical Support Team.

Yvonne Black

Technical Manager (PRRC*)



* Person responsible for regulatory compliance

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www.atomscientific.com

Certificate of Registration



Client Ref. GBR/2021/04/19

Issued To: Atom Scientific Ltd
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Hyde
SK14 4GX
UK

Legal Manufacturer [SRN: UK-MF-000046578]

Issued By: Advena Limited
Tower Business Centre, 2nd Flr, Tower
Street, Swatar, BKR 4013. Malta.

EU-REP [SRN: MT-AR-00000234]

EU Competent Authority: Malta Medicines Authority (MMA)
Sir Temi Zammit Buildings, Malta Life
Sciences Park, San Gwann SGN 3000
Malta.
Tel: +356 2343 9000
Email: info.medicinesauthority@gov.mt

Eudamed Actor ID: MT-CA-019

We hereby declare that:

- Device registrations for the medical devices mentioned within this certificate have duly been completed with the Malta Medicines Authority (MMA) the Competent Authority of Malta.
- Due to the 26th May 2021 Date of Application of Regulation (EU) 2017/745 (MDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 93/42/EEC (MDD) through Article 120 (3) of Regulation (EU) 2017/745 as amended, is legitimately permitted.
- Due to the 26th May 2022 Date of Application of Regulation (EU) 2017/746 (IVDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 98/79/EC (IVDD) through Article 110(3) of Regulation (EU) 2017/746 as amended, is legitimately permitted.


Anthony Kirby – Managing Director

Date of Issue: 26 June 2025

AR Cover Begins: 01 June 2025

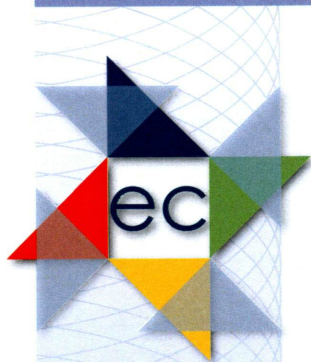
AR Cover Ends: 31 May 2026

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

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Registered in Malta No. C 76865

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The management of

Atom Scientific Limited
Unit 2A East Tame Business Park, Rexcine Way,
Hyde, Cheshire, SK14 4GX

has been assessed and certified by independent european certification limited
in respect of their Quality Management System and found to be meeting the requirements of:

ISO 9001:2015

Certification is hereby granted providing the rules and conditions relating to the certification are
observed at all times

Certification Scope:

**Manufacture, Testing and Supply of Diagnostic
Reagents and Stain Kits for the Worldwide Life
Science Industry. Supply of General Purpose
and Analytical Grade Chemicals, Solvents and
Consumables**

Date of First Issue

23rd August 2013

Date of Revision

2nd August 2025

Valid Until:

23rd August 2028

Certificate Number:

442230

EAC Number:

29/34

Authorised signature for independent european certification limited

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