

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

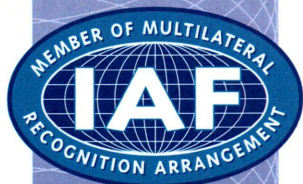
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Independent European Certification Ltd
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Pinchbeck, Spalding
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scheme rules may render this certificate invalid,
including failure to undergo periodic surveillance
visits. The use of the accreditation mark indicates
accreditation in respect of the activities
covered by the scope of our accreditation.





ISO 45001

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 Occupational Health and Safety Management System and found to be
meeting the requirements of:

ISO 45001:2018

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

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EU Declaration of Conformity

QF14.1 Revision:C

Date:

18/03/25

Declaration of Conformity

for Pathology Reagents

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Pathology Reagents
Legal Manufacturer: (Name on Label)	<u>Atom Scientific Ltd</u> 2A East Tame Business Park Rexcine Way Hyde SK14 4GX United Kingdom
SRN:	UK-MF-000046578
Basic UDI-DI:	See Appendix II
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Diagnostic aid in a professional laboratory
IVDR Classification:	Class A (Rule 5)
Notified Body:	Not Applicable for Class A
CE Certificate:	Not applicable for Class A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234



EU Declaration of Conformity

QF14.1 Revision:C

Date:

18/03/25

IVDR Assessment Route:	<i>Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.</i>
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Name Peter Keenan Position Commercial Director

Signed  Date 18/03/2025 Place Manchester, UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I – Applicable Standards

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	Basic UDI-DI	GMDN Code
RRSK	Stain Kit	505591470RRSKG4	43587
RRSP	Biological Stain	505591470RRSPGE	43587



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RRFF	Cytology Fixative Solution	505591470RRFFEK	57743
BIOM	Tissue Marking Dye	505591470BIOMAX	63615
GPS	Solvents	505591470GPSJM	63938
K1302	Stain Kit (Guest)	505591470K1302WM	43587
RRDC	Decalcifying Solution	505591470RRDCE7	57785
RRPBS	Buffered Sample Diluent	505591470RRPBSG4	58208
AE	Buffer Tablets	505591470AERG	58208
RRPL	Specimen Buckets	505591470RRPLFV	47775
PVC	Specimen PVC Plastic Jars	505591470PVCKL	47775
RRSL	Specimen Screw Lid White Jar	505591470RRSLG6	47775
RRMM	Mounting Media	505591470RRMMFN	43550
HL	Fixatives (Histolab)	505591470HLSK	63938
AS-RRSP	Stains (Histolab)	505591470AS-RRSPDP	43587

Version History

Version	Compiled by	Date	Description
1.0	Yvonne Black	29/03/2022	First issue
2.0	Yvonne Black	12/11/2024	Second Issue
3.0	Yvonne Black	18/03/25	Third Issue