Atom Scientific

Compliance Pack

2024/2025

european certification group
ISO 9001 REGISTERED FIRM
UKAS MANAGEMENT SYSTEMS
0054

Digitally signed by Ceaicovschi Tudor
Date: 2024.12.12 12:39:51 EET
Reason: MoldSign Signature
Location: Moldova

CE IVD UK CA

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Contents

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Unit 2A, East Tame Business Park, Hyde, Manchester, SK14 4GX

independent european certification ltd

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	Date of Revision	Valid Until:
23rd August 2013	**29th July 2023**	**23rd August 2025**

Certificate Number: **442230**

EAC Number: **29/34**

Authorised signature for independent european certification limited

Independent European Certification Ltd
Phone : +44 (0)1775 722 728
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42A Knight Street
Pinchbeck, Spalding
Lincolnshire
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PE11 3RB

UKAS MANAGEMENT SYSTEMS
0054

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)	**Atom Scientific Ltd** 2A East Tame Business Park Rexcine Way Hyde SK14 4GX United Kingdom
SRN:	Not yet acquired.
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
Notified Body:	Not Applicable for Class A
CE Certificate:	Not applicable for Class A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234

EU Declaration of Conformity QF14.1 Revision:A Date: 29/03/2022

IVDR Assessment Route:	*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.*

Name Peter Keenan **Position** Commercial Director

Signed **Date** 29/03/2022

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 require-ments

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

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.

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To whom it may concern

Subject: **ISO 13485**

Atom Scientific have a quality Management System manual for ISO 13485 as required by the IVDR standard. Our in-vitro diagnostic devices are 'class A' devices which means there is no requirement to be certified by a notified body to ISO 13485.

The 'Quality Policy' clause of ISO 13485:2016 states the following:

'0.2 Quality Policy -

The purpose of the Quality Management System is to ensure that the products and services provided by (the Company) to customers consistently meet or exceed their expectations and complies with applicable regulatory requirements. The company operates a system that regularly evaluates its processes and customer needs and has set quantifiable goals with plans in place to ensure that they are improved year on year.

It is the policy of the Company to maintain, on a continual basis, an effectively managed Quality Management System certified to the BS EN ISO 9001:2015 Quality Management System standard and in compliance with ISO 13485:2016. The products and services provided by the Company conform to the procedures and disciplines of the company and the bespoke needs and expectations of every customer are achieved.'

Atom Scientific are therefore in compliance with ISO 13485:2016 as required

Yvonne Black
Technical Manager (PRRC)

Date: 19/07/2024

Declaration of Conformity

for Pathology Reagents

Atom Scientific declares the above named device complies with the UK medical Devices Regulations 2002 (SI 2002 No 618 as amended) which were amended by the medical devices (Amendment etc) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020

The undersigned declares that the products described in this document meet the regulatory provisions that apply to them and the UKCA Mark may be affixed.

General Product Name:	Pathology Reagents
Legal Manufacturer: (Name on Label)	**Atom Scientific Ltd** 2A East Tame Business Park Rexcine Way Hyde SK14 4GX United Kingdom
Risk Class of Product:	General IVD
Annex Used in the Conformity Assessment	Annex III
Intended Purpose:	Diagnostic aid in a professional laboratory
Basic UDI-DI	See Annex II
Declaration:	Placed on the market under the sole responsibility of the manufacturer.

Name Peter Keenan **Position** Commercial Director

Signed **Date** 05/05/2022

Appendix I – Applicable Standards

This present declaration is also in conformity with the following Harmonized standards:

Standard/CS/Document Name	Description
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
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ISO 45001

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ISO 45001:2018

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