ABDOS

10 YEARS ABDOS LIFE SCIENCE

“QUALITY IS VITAL BUT CERTIFICATION ENSURES IT”

Certification - How valuable are these

Certificate of Registration

This certificate has been awarded to

Abdos Labtech Pvt. Ltd.

Plot No.-1, Shiv Ganga Industrial Estate, Lakheshwari, Bhagwanpur, Roorkee, Uttarakhand, 247667, India

In recognition of the organization's Quality Management System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below

Development, Manufacture and Distribution of Life Science Plastic Consumables and its related Accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Uses

Certificate Number 101054/A/0001/UK/En

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
15 October 2021	2	14 October 2024	2
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
05 October 2021	0	15 October 2018	n/a

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by — *On behalf of the Schemes Manager*

Certification & Inspection

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of EU Council Directive 98/79/EC of 27 October 1998 on (Regulation (EU) 2017/746 on in vitro diagnostic medical devices).

Certificate No.: CE-2390

Manufacturer

Name : **Abdos Labtech Private Limited**

Address : **Plot No-1, Shivganga Industrial Area, Lakheswari Bhagawanpur, Roorkee, Uttarakhand-247667, India**

Products : **Micro Tips, Micro Centrifuge Tubes, Centrifuge Tubes, Cryo Vials, Ria Vial & Cap, Sample Container, Petridishes , Pipettes, Equipment's, Tissue Culture Flask (Plate & Dishes) Gloves, Pasteur Pipettes, Serological Pipettes, Storage Vial, Beaker, PCR Tubes & Plates, Screw Cap Vial, Bioreaction Tube, Roller Bottles, Volumetric Flask, Measuring Cylinder, Bottle, Carboys, Aspirators, Freezing Tubes**

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the EU Council Directive 98/79/EC of 27 October 1998 on (Regulation (EU) 2017/746 on in vitro diagnostic medical devices)

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the referenced models.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of initial registration	25th March 2022
Date of this Certificate	25th March 2022
Certificate Expiry	24th March 2025
Recertification Due (subject to the company maintaining its system to the required standard)	24th March 2025

Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851

ISO 9001

Quality Management System

CE Certificate

Certificate of Compliance

Certification - How valuable are these

Certificate of Registration

This certificate has been awarded to

Abdos Labtech Pvt. Ltd.

Plot No.-1, Shiv Ganga Industrial Estate, Lakheshwari, Bhagwanpur, Roorkee, Uttarakhand, 247667, India

In recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Development, Manufacture and Distribution of Life Science Plastic Consumables and its related Accessories for Pharmaceutical, Diagnostic, Clinical Research and Medical Uses

Certificate Number: 101054/B/0001/UK/En

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
15 October 2021	2	14 October 2024	2
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
13 October 2021	0	15 October 2018	n/a

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

On behalf of the Schemes Manager

Obelis EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

REF. NO. : TMV 2498-2021
ORDER NO. : JC 1991-2021

DATE: 26/10/2021

MANUFACTURER: Abdos Labtech Private Limited, 13A, Government Place East, Kolkata, 700069, India

FACILITIES: Abdos Labtech Pvt. Ltd. Plot No-1, Shiv Ganga Industrial Estate, Lakeshwari, Bhagwanpur, Roorke Pin-247667, India

PRODUCT CATEGORIES: Please See Annex A - List of Devices (17 Devices, 9 Pages)

MODELS: Please See Annex A - List of Devices (17 Devices, 9 Pages)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on 01/05/2016.*

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tel. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

Registered Address : Bd. Général Wahis 53 - 1030 Brussels | Registered Office Address : Bd Brand Whitlock 30, B – 1200 Brussels - Belgium
T : + 32 (0) 2 732 59 54 | F : + 32 (0) 2 732 60 03 | Email: mail@obelis.net | Website: www.obelis.net
VA – ID : 0645116 – 22/02/2019

ISO 13485

Manufacturing of Plastic lab Ware for Clinical & Medical Use

IVD Certificate

Certified In-vitro Products

Certification - How valuable are these

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: TMV 2499-2021
Order No.: JC 1991-2021

BELGIUM

Date: 26/10/2021

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: ABDOS LABTECH PVT. LTD.

ADDRESS: PLOT NO-1, SHIV GANGA INDUSTRIAL ESTATE, LAKESHWARI, BHAGWANPUR, ROORKE PIN-247667, INDIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 19/10/2021 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (9 PAGES, 17 DEVICES)

As of the 20/10/2021, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

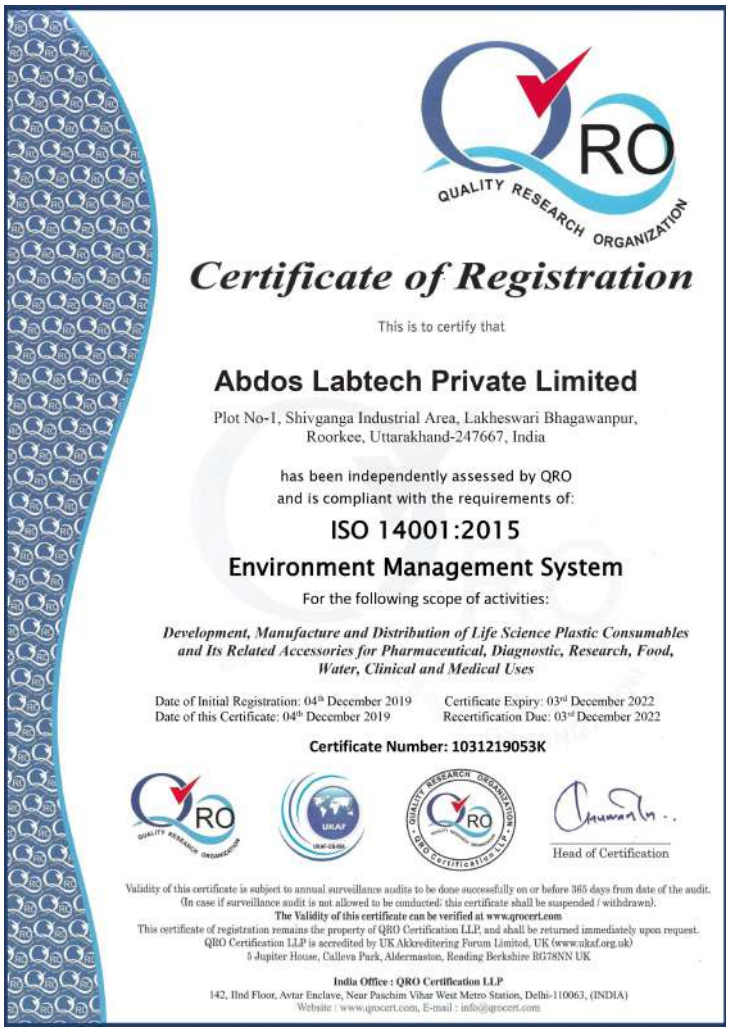
- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Mr. G. Ekayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels | Registered Office Address: Bd Brand Whitlock 30, B – 1200 Brussels - Belgium
T: + 32 (0 2 732 5954 | F: + 32 (0 2 732 6003 | Email: mail@obelis.net | Website: www.obelis.net
VS – ID : 00454716 – 22/02/2019



QRO
QUALITY RESEARCH ORGANIZATION

Certificate of Registration

This is to certify that

Abdos Labtech Private Limited

Plot No-1, Shivganga Industrial Area, Lakheswari Bhagawanpur, Roorkee, Uttarakhand-247667, India

has been independently assessed by QRO and is compliant with the requirements of:

ISO 14001:2015

Environment Management System

For the following scope of activities:

Development, Manufacture and Distribution of Life Science Plastic Consumables and Its Related Accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Uses

Date of Initial Registration: 04th December 2019
Date of this Certificate: 04th December 2019
Certificate Expiry: 03rd December 2022
Recertification Due: 03rd December 2022

Certificate Number: 1031219053K

Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit. (In case if surveillance audit is not allowed to be conducted: this certificate shall be suspended / withdrawn).
The Validity of this certificate can be verified at www.qrocert.com
This certificate of registration remains the property of QRO Certification LLP, and shall be returned immediately upon request.
QRO Certification LLP is accredited by UK Akkreditering Forum Limited, UK (www.ukaf.org.uk)
5 Jupiter House, Calleva Park, Aldermaston, Reading Berkshire RG78NN UK

India Office : QRO Certification LLP
142, IInd Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA)
Website : www.qrocert.com, E-mail : info@qrocert.com

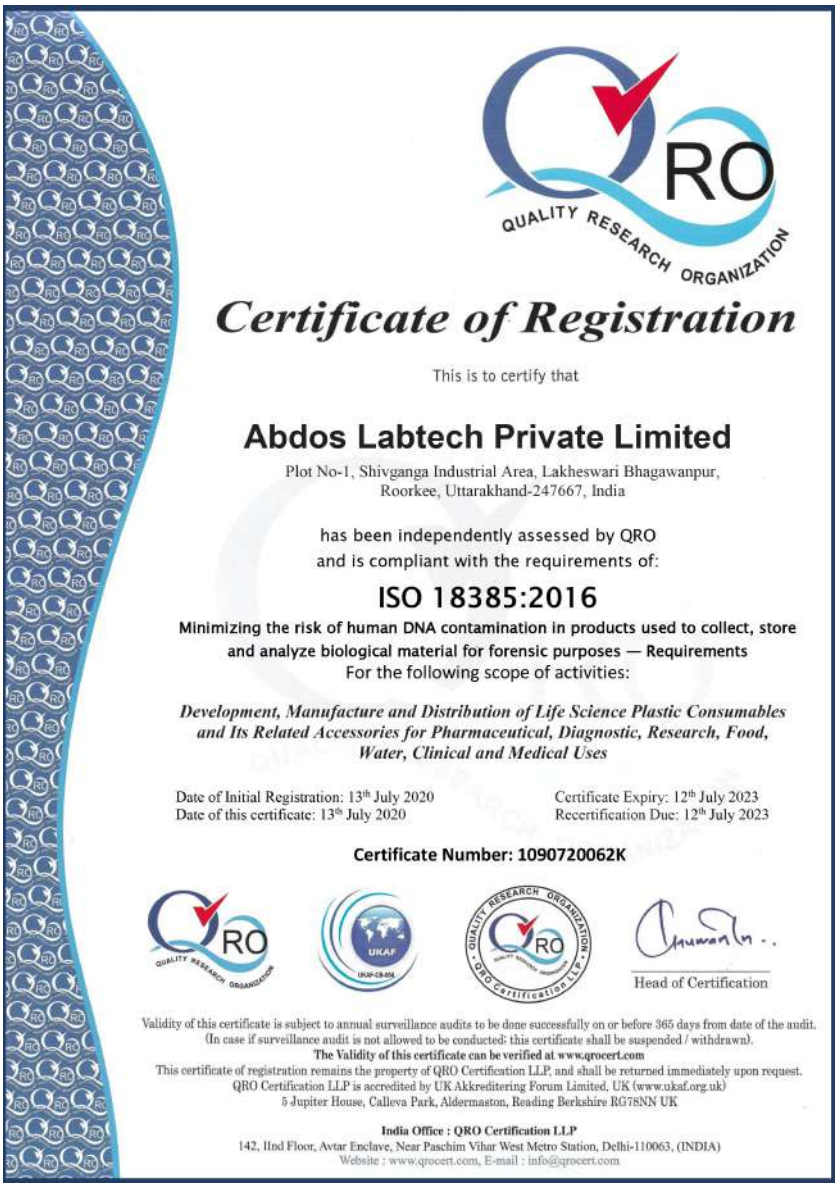
EC-REP

European Union Representative

ISO 14001

Environment Management System

Certification - How valuable are these



QRO
QUALITY RESEARCH ORGANIZATION

Certificate of Registration

This is to certify that

Abdos Labtech Private Limited

Plot No-1, Shivganga Industrial Area, Lakheswari Bhagawanpur,
Roorkee, Uttarakhand-247667, India

has been independently assessed by QRO
and is compliant with the requirements of:

ISO 18385:2016

Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements

For the following scope of activities:

Development, Manufacture and Distribution of Life Science Plastic Consumables and Its Related Accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Uses

Date of Initial Registration: 13th July 2020
Date of this certificate: 13th July 2020

Certificate Expiry: 12th July 2023
Recertification Due: 12th July 2023

Certificate Number: 1090720062K

Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit.
(In case if surveillance audit is not allowed to be conducted: this certificate shall be suspended / withdrawn).
The Validity of this certificate can be verified at www.qrocert.com
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5 Jupiter House, Calleva Park, Aldermaston, Reading Berkshire RG78NN UK

India Office : QRO Certification LLP
142, IInd Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA)
Website : www.qrocert.com, E-mail : info@qrocert.com

ISO 18385:2016

Forensic DNA

ISO 9001 - Quality Managemant System


Certificate of Registration

This certificate has been awarded to

Abdos Labtech Pvt. Ltd.

Plot No.-1, Shiv Ganga Industrial Estate, Lakheshwari, Bhagwanpur, Roorkee, Uttarakhand, 247667, India

In recognition of the organization's Quality Management System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below

Development, Manufacture and Distribution of Life Science Plastic Consumables and its related Accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Uses

Certificate Number 10105A/A/0001/UK/En			
Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
15 October 2021	2	14 October 2024	3
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
01 October 2021	0	15 October 2018	n/a

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

On behalf of the Schemes Manager

ISO 9001

Quality Management System

Celebrating 10 years of ISO 9001

ABSTRACT

ISO 9001:2015 specifies requirements for a quality management system :

A) ABDOS demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

B) ABDOS aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

CE

Certificate of Compliance

CE

Certificate No.: CE-2390

Manufacturer

Name : Abdos Labtech Private Limited

Address : Plot No 1, Shivganga Industrial Area, Lakheswari Bhagwanpur, Roorkee, Uttarakhand-247667, India

Products : Micro Tips, Micro Centrifuge Tubes, Centrifuge Tubes, Cryo Vials, Ria Vial & Cap, Sample Container, Petridishes , Pipettes, Equipment's, Tissue Culture Flask (Plate & Dishes) Glovess, Pasteur Pipettes, Serological Pipettes, Storage Vial, Beaker, PCR Tubes & Plates, Screw Cap Vial, Bioreaction Tube, Roller Bottles, Volumetric Flask, Measuring Cylinder, Bottle, Carboys, Aspirators, Freezing Tubes

Complies with the requirements applicable to it

This certificate is issued under the following conditions:

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of initial registration	25th March 2022
Date of this Certificate	25th March 2022
Certificate Expiry	24th March 2025
Recertification Due (subject to the company maintaining its system to the required standard)	24th March 2025

Authorised Signatory

CE Certificate

Certificate of Compliance

ABSTRACT

A) ABDOS is authorized CE on its Products in trade movement in the European Economic Area.

B) ABDOS Conformity with Europe demonstrates that the products have been **audited/assessed** in terms of minimum **safety, health and environmental** requirements.

C) ABDOS CE marking also indicates fair competition among manufacturers as it enforces accountability and conformity with the same requirements.

Celebrating 10 years of CE

IVD CERTIFICATE

ABDOS Cryo vials , Sample containers, & Storage vials ranges are IVD certified

IVD CERTIFIED

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

REF. NO. : TMV 24/98-2021
ORDER NO. : JC 1991-2021
DATE: 26/10/2021

MANUFACTURER: Abdos Labtech Private Limited, 13A, Government Place East, Kolkata, 700069, India
FACILITIES: Abdos Labtech Pvt. Ltd. Plot No-1, Shiv Ganga Industrial Estate, Lakeshwari, Bhagwanpur, Roorke Pin-247667, India

PRODUCT CATEGORIES: Please See Annex A - List of Devices (17 Devices, 9 Pages)

MODELS: Please See Annex A - List of Devices (17 Devices, 9 Pages)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on 01/05/2016.*

Obelis s.a. - O.E.A.R.C.
Mr. G. Ekayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53- 1030 Brussels | Registered Office Address: Bd Brand Whitlock 30, B – 1030 Brussels- Belgium
T: +32 (0) 2 732 59 54 - F: +32 (0) 2 732 60 03 | Email: mail@obelis.net | Website: www.obelis.net
V3 – ID : 0145116 – 20/02/2019

IVD Certificate

Certified In-vitro Products

Celebrating 06 years of IVD

ABSTRACT

A) ABDOS offers good quality IVDs certified products. These IVD certified products and accessories are used to perform tests on **samples**, such as **blood, urine, tissue**, of human origin to help detect **infection, diagnose a medical condition, prevent disease or monitor drug therapies.**

B) The first step is to determine if the product is a medical device as defined by the Directive. The In Vitro Device Directive Article 1, point 2b defines an IVD as any medical device which is a

•. Cryo product, containers & Storage, Instrument, Apparatus • Reagent, Reagent Product Calibrator, Control Material • Kit

• Equipment, System

C) Whether used alone or in combination, intended to used in vitro for the **examination of specimen, including blood and tissue donations,** derived from the **human body, solely or principally for the purpose of providing information:**

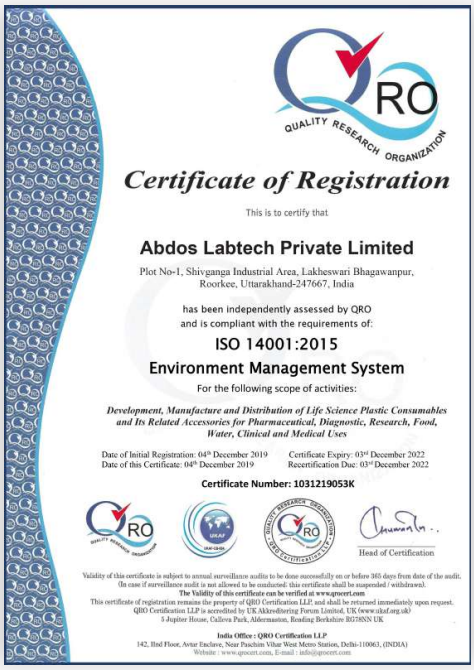
• concerning a physiological of pathological state of health or disease, or

• concerning a congenital abnormality, or

• to determine the safety and compatibility with potential recipients, or

• to monitor therapeutic measures.

ISO 14001 - 2015 Environment Management System



QRO
QUALITY RESEARCH ORGANIZATION

Certificate of Registration

This is to certify that

Abdos Labtech Private Limited

Plot No-1, Shivganga Industrial Area, Lakheswari Bhagawanpur, Roorkee, Uttarakhand-247667, India

has been independently assessed by QRO and is compliant with the requirements of:

ISO 14001:2015

Environment Management System

For the following scope of activities:

Development, Manufacture and Distribution of Life Science Plastic Consumables and Its Related Accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Uses

Date of Initial Registration: 04th December 2019 — Certificate Expiry: 03rd December 2022
Date of this Certificate: 04th December 2019 — Recertification Due: 03rd December 2022

Certificate Number: 1031219053K

Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit. (In case if surveillance audit is not allowed to be conducted, this certificate shall be suspended / withdrawn).
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India Office : QRO Certification LLP
142, IInd Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA)
Website : www.qrocert.com, E-mail : info@qrocert.com

ISO 14001

Environment Management System

NEW

ABSTRACT

ABDOS Labtech Achieves ISO 14001:2015 Environmental management systems Certification.

A) Based on ISO 14001:2015 specifies the requirements for an environmental management system, **ABDOS** is committed to enhance its environmental performance.

B)ABDOS is intended to manage its environmental responsibilities in a systematic manner that contributes to the environmental pillar of sustainability.

C) ISO 14001:2015 helps organization achieve the intended outcomes of its environmental management system, which provide value for the environment & Sustainability. **ABDOS** aims to deliver Consistent environmental policy, the intended outcomes of an environmental management system include:

- **Enhancement of environmental performance;**
- **Fulfilment of compliance obligations;**
- **Achievement of environmental objectives.**

ISO 13485 - Quality Management System

Certificate of Registration

This certificate has been awarded to

Abdos Labtech Pvt. Ltd.

Plot No.-1, Shiv Ganga Industrial Estate, Lakheshwari, Bhagwanpur, Roorkee, Uttarakhand, 247667, India

In recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Development, Manufacture and Distribution of Life Science Plastic Consumables and its related Accessories for Pharmaceutical, Diagnostic, Clinical Research and Medical Uses

Certificate Number 10350/6/0001/UK/En

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
15 October 2021	7	14 October 2024	2
Revision Date	Revision Number	Original Certificate Issue Date	Scheme Number
13 October 2021	6	15 October 2018	n/a

For detailed explanation for the data fields above, refer to http://www.ars-holdings.com/logos-and-regulations

Issued by

On behalf of the Schemes Manager

ISO 13485

Manufacturing of Plastic lab Ware for Clinical & Medical Use.

Celebrating 10 years of ISO 13485

ABSTRACT

A) ABDOS accounted for in the organization's **quality management system by monitoring, maintaining, and controlling** the processes.

B) ABDOS is committed in one or more stages of the **life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design** and **development or provision of associated activities (e.g. technical support).**

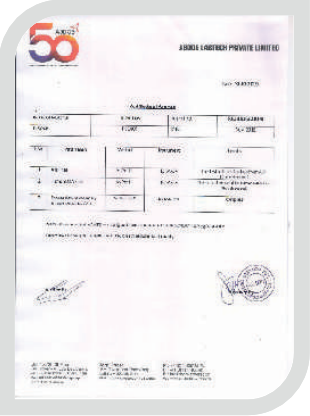
• **ISO 13485:2016** specifies requirements for a quality management system , **ABDOS** demonstrates it's ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

C) ABDOS is committed to empower 5 clauses of ISO 13485 that are numbered 4, 5, 6, 7, 8 4 **Quality management system 5 . Management responsibility 6 . Resource management 7 . Product /service realization 8 . Measurement, analysis and improvement**

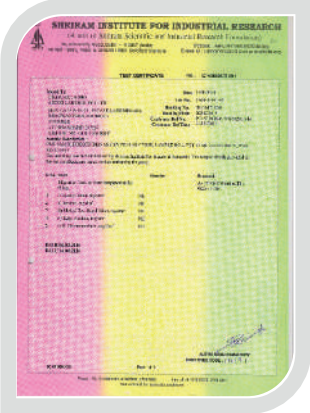
Certification - How valuable are these

Heavy Metal Free

Sterility Test Report

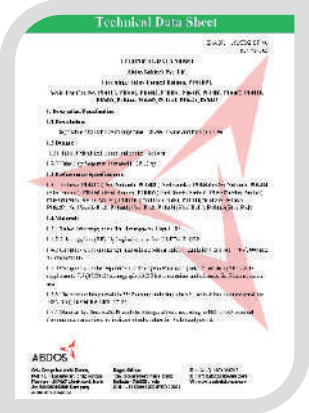


Endotoxin And ATP Free Test Report



Migration Test Report

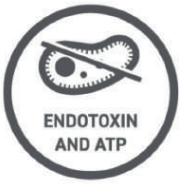
Certificate of Analysis (COA)



Technical Data Sheet

GCMS/ TOC test report

FREE



FREE

HUMAN DNA FREE

LEAK TEST

PETRDISH STANDARDS

DNase RNase & Pyrogen Free

ABSTRACT

A) **ABDOS** Confirms that all essential range is **"DNase/RNase-free".** It can be used forthe sensitive applications such as PCR & qPC R.

B) **DNase and RNase** are ubiquitous in the environment, and in some biological materials. They are present in relatively **high concentrations**. RNase frequently contaminates common molecular biological reagents such as reaction buffers, enzymes such as reverse transcriptase, RNA polymerase, and buffers for RNA purification and storage. DNase degrades DNA and its presence is a threat to many molecular biology experiments.

• A deoxy ribonuclease, or DNase, is an enzyme that degrades DNA by catalysing the hydrolytic cleavage of phosphodiester linkages in the DNA backbone.

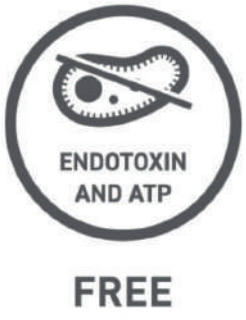
• DNase contamination can come from contact with human skin, and is often present in the lab environment.

• DNase contamination is of great concern in the medical device and pharmaceutical industries as well as the biotech and research fields, because DNase can cause degradation of valuable DNA samples, which may make it impossible to analyse the DNA via PCR, QPCR or next generation sequencing

Endotoxin And ATP Free Test Report

ABDOS achieved Endotoxin level ≤0.005 EU/ml

Endotoxin And ATP Free Test Report



ABSTRACT

A) ABDOS achievedtheendotoxinlevel **≤0.005 EU/ml** & met the criteria established in ANSI/AAMI ST 72, IP & USP, Bacterial Endotoxins –Test methodologies, routine monitoring & alternatives to batch testing. The acceptance level for product is ≤0.005 EU/ml by LAL test.

B) Endotoxins are bacterial structural components that are released when such a cell is lysed.

• These components are toxic if administered to humans and/or animals, causing a pyrogenic response (rise in body temperature). For this reason it is important it must be tested for their endotoxin content. ABDOS provides endotoxin free products in **Liquid Handling , Centrifuge , Cryo & General laboratory category.**

Gamma Sterilization : ISO 11137

STERILE R

ABSTRACT

A) Gamma radiation sterilization is the most popular form of radiation sterilization. Gamma based radiation sterilization has been deemed safe and effective by a number of government and public health agencies including the US Centre for Disease Control and Prevention, the Food and Agriculture Organization, the United Nations and the World Health Organization.

- Gamma rays pass readily through plastics and kil bacteria by breaking the covalent bonds of bacterial DNA.
- They are measured in units called kiloGrays(kGy). (ABDOS kGyis most ideal)
- Gamma irradiation provides a number of benefits in cost and sterility assurance. It can be applied under safe, well defined, and controlled operating parameters, andis not a heat-or moisture generating process.
- Environmental friendly: There is no residual radioactivity after irradiation.

DOSE VALIDATION

Gamma irradiated dose is validated according to **IS. EN. ISO 11137-2** Method 1 to confirm the **SAL 10^{-6}**. For that routine testing of bioburden & Sterility test is carried out at our manufacturing facility.

VALIDITY OF STERILITY

We assure all sterile products have been sterile through Co-60 gamma radiation with valid certified dose and has been PASSED for all sterility tests. We confirm that the Sterile product would be Sterile until unless the packing pouch is not tampered/punctured/open or 5 yrsfrom date of Radiation.

Heavy Metal Test Report

Heavy Metal Test Report

ABSTRACT

A). ABDOS recommends Heavy metal free products. Presenceof **HM** is less than 1PPM(not detectable). The sum of the incidental concentration levels of **lead, mercury, cadmium and hexavalent** chromium present does not exceed define limit of Coalition of Northeastern Governors (EU CONEG) model Toxics in Packaging Legislation.

B) ABDOS productscan be used for **storage and analysis** tasks that require extremely low levels of **most common metals..**

Migration Test Report

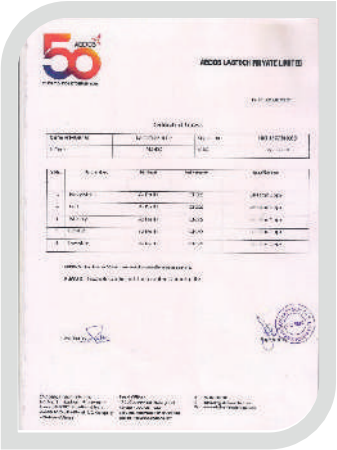
Migration Test Report

ABSTRACT

• **ABDOS** ensures **migration free product.** The Overall Migration limit (OML) applies to the sum of all substances that can migrate from the plasticcontact material to the **chemical**(or chemical simulant). The overall migration limit is a measure for the **inertness of the material.**

• Within the area of contact materials, migration limits have been set for many substances based on the toxicological risk assessment of these substances. These limits are included in Contact regulations with the aim to control the exposure to these substances to **protect the samples.**

GCMS/TOC test report



GCMS/TOC test report

ABSTRACT

• **ABDOS products** GC-MS results showed that many compounds identified in plastic-based materials are not on the positive list of the regulations.

• GC-MS is useful as a screening approach in control laboratories of compliance with legislation.

• **No organic solvent peak** was observed on GCMS during the Extractable and Leachable study with any of the **ABDOS products**.

• Total organic carbon (TOC) is performed according to BPOG guidelines (extractable testing protocols). The TOC analysis performed on **ABDOS** products complies with the prescribed standard quality.

" CERTIFIED PRODUCTS ALWAYS LEAD TO BETTER RESULTS "

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+91-11-41081897 www.abdoslifesciences.com labtech@abdosindia.com