ABDOS®
LIFE SCIENCES
Advancing Science with Quality

Quality is our
benchmark,

Certification is our
commitment

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ISO Class 8 Validated Manufacturing Facility with **Advanced Robotics & Automation!**

About Us

Abdos is a leading manufacturer and supplier of high-quality laboratory products, serving a broad range of industries including life sciences, biotechnology, pharmaceuticals, healthcare, and research institutions. With a steadfast commitment to quality, innovation, and customer satisfaction, Abdos ensures that every product meets the highest standards of performance and reliability.

Our ISO and CE certifications demonstrate Abdos's commitment to delivering high-quality, safe, and compliant products. These internationally recognized standards ensure our labware complies with strict global regulations—building trust and confidence across industries.

Our manufacturing facility is certified with WHO-GMP (World Health Organization – Good Manufacturing Practices), reflecting our unwavering commitment to global quality standards.

- Ensures that our products are consistently produced and controlled according to internationally recognized guidelines.
- Signifies adherence to strict hygiene, safety, and documentation protocols across all stages of production.
- From trained personnel and validated equipment to controlled environments and traceable processes, every aspect of our operation is designed to ensure product safety, efficacy, and compliance.
- WHO-GMP certification positions us as a trusted manufacturer in the healthcare and life sciences industry, enabling us to deliver high-quality, reliable products worldwide.

UKcert
Certification & Inspection

Certificate of Compliance

Certificate Number: UQ - 2025060709

This is to certify that

ABDOS LABTECH PRIVATE LIMITED

at

PLOT NO-1, SHIVGANGA INDUSTRIAL AREA, LAKHESWARI BHAGAWANPUR, ROORKEE, UTTARAKHAND-247667, INDIA

Has successfully implemented the Quality management System and been found working satisfactorily as per the norms of "Good Manufacturing Practice" as laid down by "World Health Organisation" which has been in conformance to the requirements of

WHO-GMP

SCOPE:-DESIGN DEVELOPMENT, MANUFACTURE AND DISTRIBUTION OF LIFE SCIENCE PLASTIC CONSUMABLES (IVD), INSTRUMENTS AND RELATED ACCESSORIES FOR DIAGNOSTIC, RESEARCH, CLINICAL AND MEDICAL USE

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced Models Products.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines.
3. The certificate validity is conditioned by positive results or surveillance audits.

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

Date of initial Registration	7th June 2025
Date of this Certificate	7th June 2025
Certificate Expiry	6th June 2028
Recertification Due	6th June 2028

Authorised Signatory

ISO Certifications
(Quality, Safety & Environment)

ISO 9001:2015 Certified Facility

Our manufacturing unit is ISO 9001:2015 certified, reflecting our commitment to quality management and continuous improvement. This globally recognized standard ensures:

- Well-documented, consistently followed processes
- Compliance with customer and regulatory requirements
- Reliable, traceable, and efficient operations

We prioritize quality at every stage-from raw material sourcing to final product delivery-ensuring consistent performance and customer satisfaction.


IQNET

Building trust together

Certificate

Quality Austria

has issued an IQNET recognized certificate that the organization

Abdos Labtech Private Limited

Plot No. 1, Shiv Ganga Industrial Estate, Lakeshwari, Bhagwanpur, Roorkee – 247 667, Haridwar, Uttarakhand, India

for the following scope

Design Development, Manufacture and Distribution of Life Science Plastic Consumables (IVD), instruments and related accessories for Pharmaceutical, Diagnostic, Research, Food, Water, Clinical and Medical Use

EAC 18.0

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 9001:2015

Registration Number: AT-32018/0

Alex Stoichitoiu
President of IQNET

Mag. Friedrich Khuen-Belasi
Authorised Representative of Quality Austria


IQNET

Building trust together

Certificate

Quality Austria

has issued an IQNET recognized certificate that the organization

Abdos Labtech Private Limited

Plot No. 1, Shiv Ganga Industrial Estate, Lakeshwari, Bhagwanpur, Roorkee – 247 667, Haridwar, Uttarakhand, India

for the following scope

Design Development, Manufacture and Distribution of Life Science Plastic Consumables (IVD), instruments and related accessories for Diagnostic, Research, Clinical and Medical Use

EAC 18.0

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 13485:2016

Registration Number: AT-00457/0

Alex Stoichitoiu
President of IQNET

Mag. Friedrich Khuen-Belasi
Authorised Representative of Quality Austria

ISO 13485:2016 Certified

Our facility is certified to ISO 13485:2016, the highest quality standard in the design, production and distribution of medical devices and related products. This globally recognized standard ensures:

- Focus on product safety, traceability, and regulatory compliance
- Ensures consistent quality from design to distribution
- Demonstrates our ability to deliver safe, effective, and reliable medical products

A mark of trust for healthcare professionals worldwide.

ISO 14001:2015 Certified

Our certification to ISO 14001:2015 reflects our commitment to responsible and sustainable manufacturing.

- Effective Environmental Management System (EMS) in place
- Focus on reducing waste, emissions, and resource consumption
- Compliance with environmental regulations and continuous improvement

Sustainability is not just a goal—it's built into how we operate.

QRO
QUALITY RESEARCH ORGANIZATION

Certificate of Registration

ABDOS LABTECH PRIVATE LIMITED

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

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

ISO 14001:2015

Environmental 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

Certificate Number: 305022120515E

QRO
QUALITY RESEARCH ORGANIZATION

Certificate of Registration

ABDOS LABTECH PRIVATE LIMITED

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

has been independently assessed by QRO and is compliant with the requirement 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

Certificate Number: 2023062044

ISO 18385:2016 Certified

We are certified to ISO 18385:2016, ensuring the highest standards in forensic-grade manufacturing.

- Controls in place to prevent human DNA contamination
- Designed for forensic and biological sample handling
- Ensures integrity, reliability, and credibility of forensic evidence

Trusted quality for contamination-free forensic analysis.

Certifications
for European Market Access

CE Certificate

- Certificate of Compliance

Ensures the product complies with essential European health, safety, and environmental protection standards

Grants legal authorization to sell and distribute products in all EEA (European Economic Area) countries.


Certificate of Compliance

CE

Certificate No.: CE-6562

Manufacturer

Name : ABDOS LABTECH PRIVATE LIMITED

Address : Plot No 1, Sitarganja Industrial Area, Lakhawori Bhagwanpur, Roorkee, Uttarakhand-247667, India

Products

Complies with the requirements applicable to it

This certificate is issued under the following conditions:

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

Date of Initial Registration	24th March 2025
Date of this Certificate	24th March 2025
Certificate Expiry	23rd March 2028
Recertification Due	23rd March 2028

Authorised Signatory


Obelis

CERTIFICATE OF IVD NOTIFICATION

BELGIUM

CE

IVD Certificate

- (In Vitro Diagnostic)

A general certificate issued under older regulatory frameworks like the **IVD Directive (98/79/EC)** in the European Union.

It confirms that a device meets the **basic requirements for safety and performance** to be placed on the EU market.

This certification applies to diagnostic products intended for in-vitro use, including certified plastic labware used in sample collection, storage, and testing.

IVDR Certificate

- (In Vitro Diagnostic Regulation)

Issued under the new European In Vitro Diagnostic Regulation (EU 2017/746), which replaced the IVD Directive.

Our certified labware is produced in accordance with IVDR, ensuring compatibility and safety for use in regulated diagnostic procedures.

IVDR certification demonstrates our commitment to global quality norms, enabling distribution across European markets.


Obelis GROUP

CERTIFICATE OF
IVDR NOTIFICATION


Certificate
OF COMPLIANCE

European Certification Council

UKCA

(Certificate of Compliance)

Applies to the quality system maintenance in the manufacture of referenced products

Declares that the technical file of the product confirms with the requirement of Medical Device Regulations 2002 (SI 2002 n. 618) (UK MDR 2002) as amended by Medical Device Regulation. (EU Exit) Regulation 2020 (MDRs 2020)

Quality and Safety Compliance

Tested and Validated for All Sensitive Applications

Dnase RNase & Pyrogen Free

ABDOS Confirms that all essential range is “DNase/RNase-free”.

Dnase and RNase are ubiquitous in the environment and in some biological materials. Their presence can degrade genetic material, leading to failed experiments and inaccurate results, It can be used for the sensitive applications such as PCR & qPCR.

FREE

Endotoxin-Free Certified Products

ABDOS products meet strict endotoxin limits of ⩽0.005 EU/ml, as per ANSI/AAMI ST72, IP, and USP guidelines using the LAL test. Endotoxins, released from lysed bacteria, can cause harmful pyrogenic reactions. Our certified lab products are tested to ensure they are endotoxin-free and safe for sensitive applications.

FREE

FREE

Gamma Sterilization: ISO 11137

We assure all sterile products have been sterilized through Co-60 gamma radiation with valid certified dose and has been PASSED for all sterility tests. 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.

Migration Test Report

The Overall Migration Limit (OML) applies to the sum of all substances that can migrate from plastic contact material to the chemical or the chemical stimulant. The OML is a measure for the inertness of the material.

FREE

Heavy Metal Test Report

ABDOS recommends Heavy metal free products. Presence of Heavy metal 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.

HEAVY METAL FREE

GC- MS/TOC test report

With GCMS analysis performed on ABDOS products showed no harmful solvent residues, and all detected compounds comply with regulatory safety lists ensuring suitability for sensitive lab use.

GC/MS Tested

TOC testing measures the amount of organic (carbon-based) compounds released from materials. For ABDOS products, this test was conducted following BPOG (BioPhorum Operations Group) extractables testing guidelines. Results confirmed that the TOC levels of within acceptable limits, with low leachability and high purity.

ISO/IEC 17025 Certified

International standard for testing and calibration laboratories. It sets out requirements for the competence, impartiality, and consistent operation of laboratories, ensuring the accuracy and reliability of their testing and calibration results.

ACCREDITED ISO/IEC 17025 LABORATORY

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
IMDR 2017 (IVD/MD)

Scan QR Code for All Certificates

What Abdos Life Sciences stands for?


Precision


Reliability


Responsiveness


Innovation


Sustainability


Relationships

Get in touch with us:

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labtech@abdosindia.com

www.abdoslifesciences.com