



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.



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.



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.



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.



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.



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”.

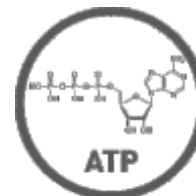
Dnase and RNase are ubiquitous in the environment and in some biological materials. Their presence can degrade genetic material, leading to failed experiments and inaccurate results, It can be used for the sensitive applications such as PCR & qPCR.



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.



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.



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.



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

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