

ISO 13485 CERTIFICATION

OUR CERTIFICATION PROCESS

Application Submission & Review:

- Submit your application to help us understand your requirements.

Stage 1 Audit (Document Review):

- Our auditors evaluate your organization's documentation, policies, and processes against the requirements of the standard

Stage 2 Certification Audit:

- Our auditors verify the implementation and effectiveness of your management system against the requirements of the standard.

Corrective Actions (if necessary):

- If any non-conformities are identified during the audits, you'll have the opportunity to address them.

Certificate Release:

- IAS grants ISO Certification post successful audit.

ABOUT THE ISO 13485 STANDARD

ISO 13485 is an internationally recognized standard for **Quality Management Systems (QMS)** in the **medical device industry**. It provides a structured framework to ensure the safety, reliability, and quality of medical devices.

ISO 13485 focuses on key principles:



REGULATORY COMPLIANCE



RISK MANAGEMENT



**DESIGN AND
DEVELOPMENT CONTROLS**



PROCESS VALIDATION



**MONITORING AND
MEASUREMENT**



CONTINUAL IMPROVEMENT

Elevate the **quality and safety of your medical devices** with ISO 13485, demonstrating your commitment to meeting stringent regulatory requirements and delivering safe products to patients and healthcare providers.



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**ACHIEVE EXCELLENCE
WITH INTEGRATED
ASSESSMENT SERVICES**



WHY CHOOSE IAS?



Our skilled auditors have over 15 years of industry experience to provide valuable insights during the certification process.



We tailor our services to meet your specific needs, ensuring a seamless certification journey.



We are with you beyond certification, assisting with maintenance and updates as your business evolves.



Our certification services are internationally recognized, giving you a competitive edge.



BENEFITS OF ISO 13485 CERTIFICATION



- Elevated customer confidence and trust through improved medical device quality
- Enhanced operational efficiency and effectiveness in device manufacturing
- Informed decision-making based on data analysis and compliance metrics
- Strengthened internal collaboration and alignment of medical device teams
- Compliance with medical device regulations and industry mandates
- Opportunities for business growth and expansion within the medical devices sector

CONTACT US



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Unlock Success with **Integrated Assessment Services**:
Your Path to Certified Excellence!