



# The QUARTET

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## SANCERT AND ISO 13485 FOR MEDICAL DEVICES

**ISO 13485** is a crucial certification for medical devices, manufacturers, and suppliers alike. It sets comprehensive requirements for quality management tailored to the industry. Compliance with this standard assures commitment to the highest standards of quality, safety, and regulatory compliance. It also serves as a foundational framework for meeting regulatory requirements, harmonizing with regulatory frameworks worldwide. **ISO 13485** certification instills confidence in the reliability and safety of medical devices and assures stakeholders that products have undergone rigorous quality assurance processes. It also facilitates access to international markets and enhances competitiveness on a global scale. If you need guidance or information related to **ISO 13485**, please contact **SANCERT** at [info@sancert.global](mailto:info@sancert.global).

### Q: What is ISO/IEC 27001?


It is a standard that specifies requirements for an Information Security Management System (ISMS). **ISO/IEC 27001:2013** and **ISO/IEC 27001:2022** have key differences. The latest version includes revised requirements to reflect changes in technology and cybersecurity threats. It offers enhanced guidance and aligns more closely with related standards. There are changes to the approach to risk assessment and treatment, and it incorporates provisions to address evolving legal and regulatory requirements. It also emphasizes the importance of resilience and continuity planning.


### GENERAL UPDATE – Climate Change and ISO

The International Organisation for Standardisation (ISO) has amended thirty-one existing management system standards to integrate climate change considerations. This development highlights the importance of environmental sustainability and resilience for businesses worldwide. This means that companies must review and update their management systems to integrate climate change considerations. **Key aspects include climate risk assessment, mitigation and adaptation strategies, stakeholder engagement, monitoring and reporting, and continuous improvement.** The integration of climate change considerations can help organisations mitigate risks and unlock new opportunities for growth, innovation, and competitive advantage.

*The primary difference between ISO/IEC 27001:2013 and ISO/IEC 27001:2022 is the updates and revisions made to ensure its relevance and effectiveness in addressing modern cybersecurity challenges and emerging threats.*

## QUality and Reliability Through Expertise and Teamwork

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