NIOSHCert | NIOSH CERTIFICATION

# ISO 13485

## MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS (MDQMS)

## ABOUT MDQMS

ISO 13485 is an internationally recognized standard for the quality management system (QMS) specifically designed for the medical device industry. This standard outlines the requirements for establishing, implementing, and maintaining a quality management system that ensures the consistent design, development, production, and distribution of medical devices while adhering to regulatory requirements and maintaining patient safety. ISO 13485 certification is specific to the medical device industry and differs from other ISO standards, such as ISO 9001, which is a broader quality management standard applicable to various industries.

## BENEFITS

- **Enhanced Quality:** ISO 13485 provides a framework for implementing a robust quality management system that helps organizations ensure consistent product quality and safety. This can lead to fewer defects, reduced product recalls, and improved patient outcomes.
- **Global Market Access:** Many countries and regions require medical device manufacturers to comply with specific regulatory standards. ISO 13485 certification is widely recognized internationally and can serve as evidence of your commitment to quality and regulatory compliance, facilitating market access in various countries.
- **Regulatory Compliance:** The standard is designed to align with regulatory requirements in the medical device industry.
- **Competitive Advantage:** ISO 13485 certification can set your organization apart from competitors that are not certified. It demonstrates your dedication to quality and safety, which can be a strong selling point when attracting customers and partners.
- **Risk Management:** ISO 13485 places a significant emphasis on risk management throughout the product lifecycle. This helps organizations identify potential risks and implement measures to mitigate them, leading to safer products and reduced liability.

## MAIN COMPONENTS

- **Quality Management System**
  ISO 13485 specifies the requirements for an organization's quality management system. This system should address various aspects of the product life cycle, including design, development, manufacturing, distribution, and post-market activities.

- **Risk Management**
  The standard emphasizes the need for risk management throughout the entire product lifecycle. This involves identifying and assessing risks associated with medical devices and implementing measures to mitigate these risks.

- **Regulatory Compliance**
  ISO 13485 helps organizations comply with regulatory requirements specific to the medical device industry. It aligns with various global regulations, including the European Medical Device Regulation (MDR) and the US Food and Drug Administration (FDA) regulations.

- **Documentation and Record Keeping**
  The standard requires organizations to maintain detailed documentation of processes, procedures, and records related to the development, production, and distribution of medical devices. This documentation is crucial for traceability and accountability.

- **Supplier Management**
  The standard also requires effective management of suppliers and external partners to ensure that the materials and components used in medical devices meet appropriate quality standards.

SUSTAINABLE DEVELOPMENT GOALS

3 GOOD HEALTH AND WELL-BEING | 8 DECENT WORK AND ECONOMIC GROWTH | 9 INDUSTRY, INNOVATION AND INFRASTRUCTURE | 12 RESPONSIBLE CONSUMPTION AND PRODUCTION | 16 PEACE, JUSTICE AND STRONG INSTITUTIONS

**BEGIN YOUR JOURNEY**

1

## UNDERSTAND ISO 13485 STANDARD REQUIREMENTS

Review ISO 13485 guideline to understand **Medical Device Quality Management Systems (MDQMS)** requirements.

2

## ESTABLISH A MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM (MDQMS)

Implement MDQMS covering:

- Storage & handling procedures
- Distribution records
- Complaint & recall processes
- Documentation & traceability (aligned with ISO 13485)

3

## APPOINT MANAGEMENT REPORESENTATIVE/KEY PERSONNEL

Assign a responsible person (e.g., Person in Charge) with relevant training and authority to manage regulatory compliance.

4

## INTERNAL AUDIT & MANAGEMENT REVIEW

- Audit your MDQMS internally to identify gaps
- Hold a management review to evaluate and improve the system.

5

## ENGAGE A REGISTERED CAB

Apply for the MDQMS assessment from CAB.

6

## MDQMS ASSESSMENT

CAB conducts:

- **Stage 1 –** Review of documented MDQMS and preparedness
- **Stage 2 –** On-site audit to verify implementation and effectiveness
- Address any non-conformities found (client role).

7

## OBTAIN MDQMS CERTIFICATE

If compliant, CAB issues MDQMS certificate of conformity.

8

## REGISTER WITH MDA (IF REQUIRED)

Submit a valid MDQMS certificate (e.g., ISO 13485) via MeDC@St as part of the application for a Manufacturer Establishment License, in compliance with MDA regulatory requirements.

## NIOSHCert aims to create impact

# collaboratively

SCAN ME

NIOSH CERTIFICATION SDN. BHD. (NIOSHCert) is a leading national certification body and a wholly owned subsidiary of the National Institute of Occupational Safety and Health (NIOSH), and the Ministry of Human Resources, Malaysia. We have a proven track record of delivering reliable and comprehensive assessments, in conformance with the relevant international standards, codes of practices, guidelines and rules and regulations. Since 2004, NIOSHCert has been a collaboratively partner in the ISO Certification journeys of Malaysia's most successful companies, government bodies, higher learning institutions and SMEs. We have helped clients create impact and give value to the world's communities through providing internationally-recognised certification services. It is our passion and privilege to be the trusted, reliable and transparent partner in helping our clients increase the efficiency and effectiveness of their businesses operations. Testimony to NIOSHCert's emphasis on customer satisfaction, our top 10 clients have been with us for an average of 10 years. OUR COMMITMENT NIOSHCert's business practices are safe, responsible, impartial, and transparent in accordance with our Core Values and ISO 17021 Principles.

SUSTAINABLE DEVELOPMENT GOALS


Realisation of the SDGs require the joint efforts from many parties. The work of NIOSH Certification, and implementation of the management systems certifications offered by NIOSH Certification are aligned with, and contribute to the achievement of the SDGs.

## CONTACT US

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