



Certified Medical Devices from A to Z

Turning These 5 Challenges into Opportunities!

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Introduction

In today's evolving healthcare landscape, the demand for certified medical devices is on the rise, driven by advancements in technology and the growing need for alternative healthcare solutions. Our white paper, "Certified Medical Devices from A to Z," dives deep into the crucial aspects of certification processes, challenges, and solutions, aimed at navigating the complexities of the Medical Device Regulation (MDR), focusing on Medical Software. "Certified Medical Devices from A to Z" equips organisations with the knowledge and resources needed to navigate the complex terrain of certification processes, turning challenges into opportunities for growth and compliance. For further inquiries or assistance, feel free to contact us at Certification Experts.

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Contact

We're here to address any questions that may arise after reviewing the document, or if you're interested in obtaining additional information or a quote.

Please feel free to contact us.

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We are happy to assist you!

Why is Certification Important?

There is an increasing demand for alternative forms of healthcare, such as preventive care, and a rising need for long-term and remote care. Technology and appropriate software play a significant role in diagnostics, treatment, and patient care. The concept of 'Software as a Medical Device' (SaMD) has led to an obligation for Certification Process by Notified Bodies and setting up Technical Files and management processes by manufacturers to ensure the safety and effectiveness of this software.

Understanding the Difference Between SaMD and SiMD

Software as a Medical Device (SaMD) refers to software as a medical device, without being physically linked to a hardware device. For example, a mobile app used for monitoring heart rate without the need for additional hardware.

Software in a Medical Device (SiMD) refers to software used as part of a medical device, where the primary function of the device is not software-related. An example is the software used in a medical device, such as control software for a medical imaging device.

The Adapted Regulation for CE Marking on Medical Devices

Organisations manufacturing or selling medical devices face various regulatory obligations. What should you consider?

- With the introduction of the Medical Device Regulation (MDR), which replaces the Medical Device Directive (MDD), there is an obligation for most SaMD products to undergo CE marking.
- Organisations are expected to submit a complete Technical File, which is thoroughly reviewed by several subject-matter experts (SME's) of the Notified Body.
- The MDR also mandates the implementation of a Quality Management System. A significant portion of these procedures falls under the Technical File.
- To ensure compliance with MDR requirements, organisations implement a quality system according to ISO 13485:2016 and seek certification.

The process of establishing both a Quality Management System and marking a medical device itself is crucial for ensuring safety. But what steps should you take to obtain these certificates?

What Challenges Lie Ahead?

The implementation of the Medical Device Regulation (MDR) has brought forth numerous challenges for your organisation. Which ones apply to your organisation?

1. Complexity in Establishing Management Systems

The MDR imposes significantly increased complexity in establishing management systems. Stricter requirements for the quality and safety of medical devices necessitate comprehensive management systems that comply with specific standards and guidelines.

2. Complexity of Compliance

Organisations must ensure awareness of all relevant regulations and correctly implement them in their business processes. Compliance complexity with the MDR requires constant monitoring of regulatory changes, demanding organisational flexibility and responsiveness to meet evolving requirements.

3. Time-consuming Document Management

The MDR requires detailed documentation regarding the design, production, and distribution of medical devices, leading to time-consuming document management. Organisations must not only generate necessary documentation but also ensure secure and reliable storage, accessibility, and version control, placing additional burden on personnel.

4. Inefficient Process Improvement

MDR implementation necessitates improving existing processes to meet new standards and regulations. However, efficiently implementing these process improvements can be challenging. Organisations may need to revise operational procedures, provide employee training, and implement new quality control measures, potentially disrupting daily operations.

5. Managing Risks and Improvement Processes

The MDR emphasises proactive identification and management of risks related to medical devices, posing a challenge for organisations to establish systems for effective Risk Management and initiate continuous improvement processes. This requires not only implementing suitable tools and methodologies but also fostering a culture of evaluation and improvement, prompting organisations to reconsider and adjust their approach to Risk Management and improvement processes.

We believe that establishing the right processes tailored to your organisation also presents opportunities. In the next section, we elaborate on this further.

In This Whitepaper

- ✓ We address the various challenges arising from the MDR.
- ✓ We explain what it takes to establish a Quality Management System.
- ✓ We outline the steps for certifying the medical device (SaMD).
- ✓ We introduce you to an all-in-one solution.

Check it out
[certification-experts.com](https://www.certification-experts.com)

Establishing a Quality Management System: What's Involved?

One requirement of the MDR is establishing a Quality Management System (QMS) for manufacturers of medical devices, and in some cases, for distributors or importers. Even if it is for your company not legally obligated to establish a QMS, it can still be valuable; the presence of a QMS may be required by suppliers or customers.

The Essence of a QMS

Certification of Software as a Medical Device (SaMD) requires a well-implemented Quality Management System. This includes developing, implementing, and maintaining procedures to ensure compliance with regulations and standards.

Additionally, a company is responsible for verifying the effectiveness of the implemented QMS. Verification activities may include internal audits and management reviews, all aimed at ensuring the QMS is truly effective. The use of the harmonised standard ISO 13485 is a common approach to demonstrate compliance with quality management requirements in the medical device industry.

Risk Management

A crucial aspect of certification is identifying and managing risks. A structured Risk Management system is employed to minimise potential hazards to patients and users. A well-established QMS can identify potential risks and take effective measures to mitigate them.

To assess, evaluate, and control risks, hazards from various sources need to be identified and mitigated, such as:

- ✓ User-based
- ✓ Environment-based
- ✓ Application-based
- ✓ Security-based
- ✓ Device-based

To provide a better understanding of potential risks, we illustrate a few examples.

For instance, if a company manufactures medical devices like an Advanced Medical Monitoring System:

- **Usability-based:** The system is operated by medical personnel. A risk could be user errors leading to incorrect settings, potentially harming the patient.
- **Application-based:** The monitoring system is utilized for patients with diverse medical needs. A risk might be the system not effectively responding to changes in the patient's vital signs.
- **Device-based:** Technical failures in the monitoring system may result in interruptions in monitoring, potentially harmful to the patient.
- **Environment-based:** Some software applications, especially those involving complex algorithms (e.g., machine learning models), require substantial computational resources, which in turn consume more energy and contribute to environmental strain.
- **Security-based:** The monitoring system utilizes wireless communication. A risk might be unauthorized access disrupting the system's operation.

If we consider another example, such as when a company produces products like a healthcare app:

- **Usability-based:** The app interface is designed for patients and caregivers to track health metrics and receive alerts. A risk may be user errors in inputting data or misinterpreting alerts, potentially leading to incorrect actions or delayed care.
- **Application-based:** The healthcare app is intended for managing chronic conditions like diabetes or hypertension. A risk may be the app not effectively detecting or responding to fluctuations in the patient's health status, leading to inadequate management of their condition.
- **Device-based:** Technical failures or software bugs within the app may cause disruptions in data collection, transmission, or analysis, potentially resulting in missed health updates or erroneous recommendations.

- **Environment-based:** The app is used across various settings, including home environments with different internet connectivity levels. A risk may be environmental factors such as poor internet connectivity or device compatibility issues affecting the app's functionality and reliability.
- **Security-based:** The healthcare app utilizes cloud storage and may incorporate telehealth features. A risk may be unauthorized access to patient data or breaches in communication channels, potentially compromising patient privacy and trust in the platform.

ISO 14971 is the internationally recognised standard for Risk Management in medical devices. This harmonised standard establishes principles and guidelines for conducting a structured Risk Management process throughout the entire lifecycle of a medical device.

Technical Documentation and Registration

Comprehensive technical documentation is also crucial in establishing an effective Quality Management System. Developing technical documentation and meticulously maintaining records are integral parts of the Quality Management System, ensuring traceability and transparency.

A Well-functioning QMS as a Strategic Investment?

In the complex landscape of medical devices, establishing a Quality Management System is not only a legal obligation but also a strategic investment in the safety, effectiveness, and performance of products and processes. It requires dedication, precision, and continuous evaluation to meet the dynamic requirements of laws and regulations and maintain the trust of customers and stakeholders.



Certification Experts is your go-to partner for MDR compliance solutions. With over 25 years of experience and a dedicated team of specialists, we navigate the entire CE marking process for medical devices.

What's Involved in Certifying the Medical Device (SaMD)?

In general, affixing a CE marking as a manufacturer signifies compliance with all relevant safety and performance requirements for a medical device. To specifically obtain a CE marking according to the Medical Device Regulation (MDR), the product must be classified as a medical device based on the relevant risk class.

The 6 Essential Steps for Certification



Step 1

Qualification and Classification of the Medical Device or SaMD

The first step involves substantiating the qualification and justifying the classification of the medical device or SaMD.



Step 2

Implementation of a Quality Management System

A Quality Management System is established and implemented in accordance with EN-ISO 13485. Including implementing Risk Management, Post Market Surveillance and Clinical Evaluations according to the MDR requirements.



Step 3

Preparation of Technical Documentation

This step includes fulfilling general safety and performance requirements, clinical evaluation, post-market surveillance procedure, instructions, labelling, and marking.



Step 4

Registration Obligations

The registration of your organisation, PRRC, devices (Unique Device Identification/UDI) and, if needed, the involved economic operators are required. Please note the registration of your organisation and PRRC is needed at the beginning of the process and the registration of the certified devices, and the Notified Body is the final step.



Step 5

Preparation of EU Declaration of Conformity and Affixing CE Marking

The EU Declaration of Conformity will need to be prepared, along with providing instructions for affixing the CE marking in accordance with MDR requirements.



Step 6

Certification of the Quality Management System and EC Certification of your medical device

To validate the Quality Management System an internal audit needs to be performed before the final certification procedure by the Notified Body.

As you can see, there are several aspects to consider in optimising this process for your organisation. In the following section, we'll discuss a solution that guides you through setting up a Quality Management System and achieving CE marking for Medical Devices, SaMD, and SiMD.

How Certification Experts can help your organisation!

Welcome to Certification Experts, where we specialize in guiding companies through the challenging processes of setting up Technical Files, achieving CE marking for your products, and implementing ISO 13485 / MDR Quality Management Systems.

Our dedicated services for medical devices ranging from Class I to higher classes, ensuring full compliance with MDR requirements. By teaming up with our Experts for your medical device CE marking needs, you can trust on the establishment and maintenance of a certified Quality Management System, alongside a product that meets all compliance standards.

This important relationship between a certified QMS and compliant products strengthens the quality and safety of your medical devices, ultimately safeguarding the market and ensuring customer satisfaction. Trust our team of experts with the use of SmartManSys to navigate the complexities and elevate your products to meet the highest standards.

Introducing SmartManSys

Certification Experts and BMGRIP, both part of the Kader Group, operate as one team to assist your organisation in establishing a Quality Management System and obtaining CE Marking for Medical Devices, SaMD, and SiMD. The Quality Management System is designed to facilitate independent navigation through the certification process. By combining a smart digital platform with our Medical Device experts we provide a all in one solution to sell your products successfully.

SmartManSys is a digital platform that seamlessly documents process and product requirements, emphasizing process execution and continuous improvement within your organisation. The software simplifies the maintenance of Quality Management Systems, allowing for the integration of multiple systems.

- Examples of process certification: quality (e.g., ISO 9001, ISO 13485), information security (e.g., ISO 27001, NEN 7510), and privacy (e.g., ISO 27701).
- Product certification examples: machinery (e.g., Machinery Directive, CE markings) and medical apps (MDR, CE markings).

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About Certification Experts

Certification Experts is part of Kader Group within the Business Unit Consultancy & Interim, Product Compliance. As an integral part of Kader Group, our mission is to assist our clients in enhancing the quality of the living environment. Since our establishment in 1995, Certification Experts has been dedicated to facilitating business expansion into new markets while ensuring the safety of our clients' products. We provide specialised expertise and compliance services covering a wide range of product safety requirements. From CE marking to US-compliance and beyond, we empower product designers, manufacturers, exporters, importers, and distributors to penetrate their target markets successfully. Our extensive knowledge comes from combining technical and legal skills, which we use in areas such as product safety, design, quality assurance, technical documentation, and testing facility utilisation. We believe safer products are better products, advancing and improving our interactions with everything around us.



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