FIVE WAYS MEDQDOC ADDS VALUE FOR MEDICAL DEVICE DISTRIBUTORS

MDR 2017/745 has increased the regulatory and quality compliance workload for medical device companies, including distributors, by introducing more and stricter requirements.

explore more: medqdoc.com/why_medqdoc

medQdoc

With our medical device industry experience, we know that fulfilling these new demands can feel overwhelming and time-consuming, and like it doesn't add value to your business.

However, complying with the latest regulations and standards can give you a competitive advantage and improve the operation of your company.

To help you on your compliance journey, we have developed MedQdoc – a unique platform designed for the medical device industry to meet the requirements of MDR.

With practical and sustainable solutions, MedQdoc offers a simple, effective option to help medical device distributors with their QMS (Quality Management System) and add long-lasting value to their businesses.

Read on to learn how implementing an eQMS can support you in gaining a competitive advantage and adding value to your business, while helping you fulfil the requirements of MDR 2017/745.

The specific requirements for distributors are set out in MDR Article 14, General obligation of distributors, which is included at the end of this document.

medQdoc

Your MDR responsibilities as a medical device distributor

- Ensure that a Declaration of Conformity has been issued and that the device is CE-marked
- Ensure that the importer fulfils their obligations
- Ensure that the Instructions for Use (IFU) are included when the products are distributed to customers
- Ensure that the device storage and transport conditions are fulfilled
- Establish a process to handle nonconformities in accordance with the regulations
- Establish a process to handle customer complaints and medical device reporting

The risks of not having a QMS

A weak, or lack of, QMS can have a number of negative consequences for your business:

Insufficient or non-existing records and traceability can severely **increase your workload**, for example when handling a recall.

Not maintaining an adequate process and traceability for handling customer complaints could **harm the relationship** with your suppliers if such information is ever required.

If audited by a competent authority and they assess that you lack regulatory compliance, it could **impact your ability to continue operating**.

Choosing not to invest in a QMS that can help you fulfil MDR can cost you significant time and money, and lead to inefficiencies or potential damage to your business.

With our vast experience in regulatory and quality compliance, we developed MedQdoc to provide a solution for you at an affordable cost. As well as adding regulatory compliance to your organisation, it helps save time and drives the efficiency of your business.

With MedQdoc's ready-to-use system, you can start implementing a streamlined eQMS from day one, and gain instant value.

explore more: medqdoc.com/why_medqdoc

medqdoc

Why is MedQdoc so valuable to medical device distributors?

As well as mitigating the risks associated with having an insufficient QMS, there are five key ways in which MedQdoc can add value to you as a medical device distributor.

01

The tools and templates ensure you fulfil MDR requirements

MedQdoc includes 130 ready-to-use templates created by our compliance experts. These are mapped against the regulatory requirements for medical devices, making it straightforward to see exactly what information and documentation is required for each section to ensure your compliance.

This means that you can use the template documents straight away, knowing that the resulting documentation will conform to the mandatory requirements.

Download the lists of templates available via MedQdoc for MDR, IVDR, ISO 13485 and QSR below.

02

MedQdoc streamlines your regulatory and quality compliance work

As well as providing you with a system for regulatory compliance, MedQdoc enables you to improve your internal processes by simplifying documentation procedures and providing a central repository for information. This provides consistency across the company and ensures all your staff are working to the same processes.

MedQdoc's document management features can significantly streamline workflows, and the ready-to-use templates ensure standardisation across your documentation. By working within the same system, it increases your team's awareness of your regulatory responsibility and their understanding and application of compliance activity.

03

You'll save time and money on your QMS

In the past, quality management systems were often expensive and complex to implement, making it hard to justify their business value. However, with the evolution of the standardized electronic QMS (eQMS), you can now implement a QMS within a short space of time and with lower effort than before.

MedQdoc provides short implementation, providing short implementation schedules and easy adoption for most businesses, with the ability to get up and running almost straight away. Using MedQdoc will save you considerable time and money in the long term, as it helps drive more efficient regulatory and quality management processes and reduces the amount of time and effort involved in creating documentation and preparing for audits.

04

MedQdoc demonstrates your trustworthiness

As a medical device distributor, your reputation is crucial to the success of your business.

Having a robust eQMS in place not only helps demonstrate your trustworthiness and reliability as a distributor of high quality medical devices, but also provides peace of mind for your customers if they have any questions or concerns.

Implementing MedQdoc also enables you to give confidence to your suppliers and manufacturers that you meet regulatory and quality compliance, and a guarantee that you have full traceability of the medical devices you have placed on the market.

05

MedQdoc facilitates audits by external parties

As a medical device distributor, it's important to be prepared for possible audits by competent authorities, and to have the correct documentation available at any time.

Having MedQdoc in place means that you'll be able to quickly and easily locate your regulatory documentation without needing to spend significant time and effort compiling the required information when a request is received.

Your suppliers or customers may also require information from you to satisfy their own audit processes, so having a clear system in place will enable you to provide a quick, efficient response.

Contact us today to discuss how we can support your eQMS journey

READ THE FULL MDR 2017/745 ARTICLE 14 BELOW

Ref. MDR 2017/745

Article 14 General obligations of distributors

1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. Before making a device available on the market, distributors shall verify that all of the following requirements are met:
(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;
(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);
(c) for imported devices, the importer has complied with the requirements set out in Article 13(3);
(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

6. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

MEDQDOC
AT A GLANCE

MedQdoc quickly and effectively guides you through your QMS journey:

+ **Designed for the medical device industry**
+ **Ready-to-use QMS software**
+ **Enables regulatory compliance**
+ **Over 130 ready-to-use templates**
+ **Validated eQMS solution**

COMPLY EASILY WITH

- **ISO 13485**
- **ISO 14971**
- **MDR 2017/745**
- **IVDR 2017/746**

medQdoc