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1 Overview of MedQdoc https://eqms.medqdoc.com/medqdoc-internal-link/Document/449/latest/New_Tab

The intended purpose of MedQdoc is to be a tool for organisations operating in medical device industry to manage their business processes across the whole organisation.

MedQdoc is a SaaS-based document and case management solution designed for the medtech industry as part of an electronic quality management system (eQMS). The system is used to manage, store, and track essential documents in the medical device field, ensuring compliance with strict regulatory requirements such as ISO 13485 and FDA 21 CFR Part 11. [fdsgdfgdfg](#)

2 Conclusion

<https://www.ilovepdf.com/download/5mtfpzdmydAlghkmjk1rm505f6v6Ag0v8mfs5yths18fpdAc2shxgy8w840prpcpzkdAct41w7bh4js9m9l7lgx2jfm619sqfz9y02t4yh38cmmgxn2jkp6rrvxmkl15y34bkj585k9lm4908cyA0snm7qrvk46yqAA1n52l8bd1k4z9br61/67w>

The risk analysis performed on MedQdoc identified several potential vulnerabilities and areas of concern that could negatively impact system reliability, data integrity, and adherence to regulatory standards. These risks were evaluated, and appropriate mitigation strategies has been implemented to address each identified issue.

Through the application of these risk mitigation measures—such as regular backups, thorough testing, compliance assessments, and ensuring supplier reliability—the overall system integrity and operational performance have been significantly enhanced.

Following these actions, the reliability of the system and the safeguarding of data integrity have been thoroughly reassessed. Based on this, it can be concluded that the residual risks fall well within acceptable limits, both in terms of operational functionality and regulatory compliance.

Given these findings, MedQdoc is now considered to meet necessary criteria for safe and secure use, and is deemed ready for release to customers, with confidence in its ability to perform reliably in real-world applications.

3 Summary

All remaining risks are assessed accepted. Existing surveillance and monitoring activities are assessed as sufficient to continue maintaining control of the risks.

The MedQdoc software does not directly cause serious injury or death to a patient, operator, or bystander. It is a tool that is used for document control and training management, replacing the need for physical signing of documents and records for medical devices. The software named MedQdoc is therefore assessed to be of low level of concern.

The risk analysis provides a detailed overview of potential risks associated with MedQdoc, a document management system within the medtech industry. By identifying, classifying, and addressing these risks, MedQtech AB can ensure high security, compliance, and operational reliability, which is crucial for maintaining trust and meeting regulatory requirements.

The risk analysis should be updated continuously to reflect new risks and changing conditions.

4 Monitoring and follow-up

Risks should be continuously monitored, and any new risks should be added to the risk analysis as they are identified. Regular meetings should be conducted to review and update the risk analysis to ensure it remains current and comprehensive.

Customer feedback and support issues are critical elements for monitoring and following up on risks within MedQdoc. This feedback may relate to previously identified risks, or in some cases, lead to the identification of new or evolving risks, which should be documented and analyzed to improve future risk management efforts.

A periodic review of the risk analysis and the effectiveness of the implemented mitigation measures should be performed at least once a year, or more frequently if there are significant changes in business or technology conditions. The result of the periodic review shall at least be presented during management review.

4.1 Participants in risk work

- Therese Albinsson, CEO, Product Realization Manager, Product Owner
- Hilda Palm, Customer Support Manager
- Sofie Petersson, Quality and Regulatory Manager
- Mårten Nilsson, CTO, Chief Technology Officer, External resources Saas Innova AB

5 References

MedQdoc Risk Analysis ([#MQ.1779](#))

MedQdoc Validation Report ([#MQ.1922](#))

6 Document history

Version	Information	Created by (name/role)	Change management
1	First version of this Risk Management Report	Therese Albinsson, CEO, Product Realization Manager, Product Owner	N/A, first version
2	Updated Case management	Therese Albinsson,	No additional actions

	module included	CEO, Product Realization Manager, Product Owner	needed when updated. The result of the risk management report do not have any impact on the product or QMS that not previous addresses before updating this record.
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