

Risk Management for SaMD / MDSW

The assessment and management of risks associated with Software as a Medical Device (SaMD) and Medical Device Software (MDSW) differ significantly from those associated with hardware devices alone.

Although **ISO 14971** describes the risk management process and tools for medical devices, it originated with hardware medical devices. While ISO 14971 covers all core aspects of risk management for **SaMDs** and **MDSWs**, there is an additional set of standards specific to this field, including those for software lifecycle management, interoperability, cybersecurity, and more.

Risk management is a key activity in the planning and development of SaMDs and MDSWs. **Risk mitigation** measures directly influence the architecture, design, and set of functionalities of such software. If risk management is not performed correctly or with an inappropriate level of detail and expertise, costly and time-consuming changes may be necessary at a later stage.

For startups and small-to-medium-sized medical device companies facing time pressure, budget limitations, and a lack of skilled workers, risk management poses an existential threat to product development and delivery.

As your trusted partner, wega helps **small-to-medium-sized** and **startup medical device software companies** to achieve pragmatic and effective risk management, enabling them to overcome the challenges posed by evolving technologies and a lack of in-depth specialised knowledge.

We Offer:

Risk management plan development: activities follow a structured plan aligned with your product development.

Initial risk assessment: identify main risk categories, scope, and applicable standards/regulations.

Risk workshops: with your experts, we identify risks and define mitigation strategies.

Risk management file: we create and maintain documentation, updated through development and testing.

Employee training: we train your team on tools and best practices.

Documentation audit: already have a plan and file? We review for completeness and compliance.

