

# Quality policy



## 1. Background and purpose

Evira makes a commitment to its customers and users that our products will meet the requirements and expectations that are reasonable given the product's purpose and according to our marketing.

We believe that maintaining good quality is not only a fundamental requirement for providing medical devices but also a basic prerequisite for our company to achieve our overall goals and thereby contribute to satisfied customers, sustainable development, and long-term competitiveness.

This quality policy is part of the company's quality management system and should reflect the company's view on quality. The quality policy is a superior document to the Information Security Policy.

## 2. Quality management system

The development of the company's products takes place in accordance with a quality management system in accordance with ISO-13485 for medical devices. The quality management system puts requirements on, among other things, development processes, distribution of responsibilities, testing, support and error handling, follow-up as well as reporting to authorities and customers.

## 3. Guidelines and principles

Evira commits:

- to continuously work on knowledge and competence development,
- to seek help from external experts when needed,
- to work preventively with risk analysis and testing,
- to ensure that product quality and related work is a natural and integral part of the company's routines, and
- to regularly revise and update management systems, security measures, and crisis management plans.

## 4. Monitoring and revision

This policy and other quality management routines should be reviewed and updated continuously or if significant changes occur within the company or in the world. The review aims to ensure the policy's relevance and accuracy, as well as to ensure there is ongoing awareness of the policy and other routines within the organisation.



## **5. Validity of the Quality policy**

The policy was revised by the company's management team and owners on 2023-09-01 and is valid until 2026-02-28.

