Company info

care of sweden
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Care of Sweden places great importance on quality and patient safety

The medical technology company Care of Sweden has had a strong commitment to quality, patient safety, and regulatory compliance since its inception. With early ISO certification and constantly increasing industry demands, the company has developed its processes to ensure that their products not only meet standards but also enhance patient safety. By combining sustainability and quality, Care of Sweden aims to eliminate pressure ulcers/injuries and deliver long-term solutions for both individuals and society.

Focus on patient safety and quality

ISO certifications and standards are now standard features in most business operations, but this was not always the case. Since its inception, the medical technology company Care of Sweden has made quality, patient safety, and customer focus central to its operations. As early as 2007, the company was certified according to international quality standards, laying the foundation for their strong focus on compliance and safety.

Susanne Andersson, responsible for quality and compliance, has been employed at Care of Sweden since 2010. Since 2021, the Quality Management System department, QA/RA, has grown from one to four employees, reflecting the increasing importance of compliance within medical technology.

"The demands have grown, and our focus on compliance has intensified," notes Susanne.

Care of Sweden was an early adopter of ISO certification. Between 2007 and 2015, the company was certified under an environmental standard, ISO 14001, and two quality management standards, ISO 9001 and ISO 13485, the latter specifically for medical devices.

"After the update of ISO 9001 in 2015, we decided to let go of 9001 to focus solely on the industry-specific standard. Today, our work with management systems covers both quality and environmental aspects, in accordance with ISO 13485 and ISO 14001," says Susanne.

The significance of quality certification

ISO certification serves as a quality stamp indicating that the business follows international standards. This not only creates security for customers and partners but is also a requirement for operating in the global market.

"The certificate is proof that we work according to established methods, which affects not only quality but also patient safety," says Susanne.

By following well-structured processes, the company can identify and manage risks, which in turn reduces the risk of production errors and enhances patient safety. Internal audits also ensure that both data and product performance are monitored and analyzed.

New regulations for traceability and safety

In recent years, the requirements for medical devices have tightened further. Since the introduction of MDR (Medical Device Regulation) in 2021, standards and regulations have gained increasing importance for companies operating in this sector.

"MDR imposes higher demands than previous directives and has increased the focus on traceability and labelling," explains Susanne.

Care of Sweden's products are classified in risk class 1, and the company is now working to implement UDI (Unique Device Identification), which will further improve traceability of both CE-marked products and their components.

Focus on sustainability and long-term goals

For Care of Sweden, quality and sustainability are inseparable concepts. The company's overarching vision is to eliminate pressure ulcers/injuries – something that requires both innovative and high-quality products.

"Good quality means long durability, and we see our products as part of a larger, long-term effort," says Susanne.

With constantly increasing demands on both quality and sustainability, the company plans to continue being at the forefront, including through the introduction of Environmental Product Declarations (EPD) and life cycle analyses.

"We strive to meet the highest standards, and we also expect updates to ISO 13485 where we see a small gap in the current edition, which will be an exciting development for us," concludes Susanne.

Small glossary

Compliance: Regulatory compliance
QA/RA, Quality Assurance/Regulatory Affairs: Can be translated as "quality assurance" and "regulatory requirements"
MDR: A new regulation, Medical Device Regulation, which came into effect in May 2021.
UDI, Unique Device Identification: A method for labelling and identifying medical devices.
EPD, Environmental Product Declaration: An environmental product declaration including product data sheets, method choices, and results from environmental impact assessments.