

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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Medistri SA Certified with ISO 9001 - Medistri

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At Medistri, we believe our commitments are both ambitious and necessary. To achieve our objectives, we focus on scalable innovation. Designing and implementing new technologies, mobilising financing structures, and rapidly deploying renewable energy.

ISO 9001 is a globally recognized standard for quality management. It helps organizations of all sizes and sectors to improve their performance, meet customer expectations and demonstrate their commitment to quality. Its requirements define how to establish, implement, maintain, and continually improve a quality management system (QMS).

The quality management system is central to the ISO 9001 standard. At its most simple, a quality management system is a set of principles or guidelines for standard operating procedures that you can use to measure the "quality" of various aspcts of your business.

The Quality Management System, which is often referred to as a QMS, is a collection of policies, processes, documented procedures, and records. This collection of documentation defines the set of internal rules that will govern how Medistri creates and delivers products or services to the customers. The QMS must be tailored to the needs of Medistri and to the service we provide, but the ISO 9001 standard provides a set of guidelines to help make sure that Medistri do not miss any important elements that a QMS needs to be successful.

Being certified with ISO 9001 means that Medistri will be able to improve our processes and areas such as:

- Faster production due to efficient resource management.
- Eliminated or reduced problems and anomalies.
- Reduced manual work with process integration and process automation.
- Improved organizational efficiency and effectiveness by using data and evidence to inform decision making.

Organizations that are ISO 9001 certified have successfully implemented a quality management system in accordance to all of the requirements detailed in the ISO 9001 standard.

Part of the ISO 9001 certification is making sure areas for improvement are identified and acted on. As such, organizations with ISO 9001 certification can be assumed to provide products and/or services that meet strict quality management standards.

Respecting these quality management standards will ultimately result on better results for our customers such as:

- Quicker and more efficient answer to our customer satisfaction and feedback.
- Proactive solutions guarantee that issues are resolved before they even become a concern for our customers.
- Improved customer experience.

At Medistri, we understand that our team engagement is key to have one common objective. We implemented ISO 9001 also thinking exactly on our team, since ISO 9001 comes with an array of benefits for Medistri's team on the following areas:

- Improved team performance, productivity and engagement.
- The process is more clear.
- Reduce inefficiencies and improve workflow.

In order to be certified with ISO 9001, organizations must make part of a specific auditing process, where they need to build and implement a quality management system in accordance with the principles of the latest ISO 9001 standard.

The latest standard of ISO 9001 is ISO 9001:2015. However, there was an update in September 2019 known as ISO 9001:2019. This version did not introduce any major changes but included some clarifications and improved compatibility with other standards. As of the systematic review undertaken in 2020, no further revision to ISO 9001 has been agreed or started.

Also, in order to be certified with ISO 9001, organizations must have an audit performed by a Certified Body to assess the performance of your QMS against the latest ISO 9001 standard. If a organization is successful, the certificate will need to be re-certified after three years (and every subsequent three years) to make sure organizations are still up to standard (as well as any new changes to the standard).

Medistri is the largest independent sterilisation company in Europe and its mission is to facilitate innovaton in the global health sector. Since its foundation in 2006, the company has continued to grow into one of the leading providers of contract sterilization & laboratory services for healthcare companies. Medistri has grown to become a dependable partner for businesses in the pharmaceutical, medical device, aerospace, and biotechnology sectors.

- Medistri's headquarters are located in Domdidier, Switzerland. For more information, please visit www.medistri.swiss or contact contact@medistri.swiss.
- The Medistri Team

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