

Quality Policy

The mission of Rethink Medical S.L. is to provide customers – healthcare institutions / professionals and patients - with safe, innovative, and effective medical devices, that can enhance the quality of life and health of its users.

The management of Rethink Medical S.L. has implemented a Quality Management System based on the requirements of the UNE-EN-ISO 13485 standard and Regulation 2017/745 on Medical Devices. The Quality Management System currently covers the activities of: "Design, development, manufacturing and distribution of urethral catheters and non-sterile accessories / components".

The purpose of the Quality Management System is to maintain the effectiveness of the system and the proper functioning of the organization. To this end, Rethink Medical works daily to ensure the required level of safety and quality.

To achieve this, the management of Rethink Medical S.L. commits to the following general objectives:

- Commitment to comply with the applicable legal requirements, in addition to meeting customer requirements and the requirements of the implemented Quality Management System.
- Commitment to maintain the implemented Quality Management System, also taking advantage of the opportunities for improvement, ensuring all the resources necessary in a sustainable manner.
- Commitment to effectively control our activities, emphasizing the quality and safety of our products, customer service and customer satisfaction.
- Commitment to identify and eliminate sources of error, gradually reducing the number of non-conformities and customer complaints.
- Commitment to promote an understanding and dissemination of our Quality Policy within our organisation through ongoing communication with our employees.
- Commitment to provide and promote personal and professional development through an appropriate training plan for each and every member and collaborator of the Rethink Medical S.L. team.

The management of Rethink Medical S.L. makes this Policy known to all members of the organization as well as other interested and/or involved parties.

A handwritten signature in black ink, appearing to read "Szilvia Endrényi".

Szilvia Endrényi
CEO Rethink Medical S.L.

Gran Canaria, 20th December 2025