

	INTEGRATED MANUAL & MANUAL 13485	
	Section 5	Rev. 01
	All. 53/A - QUALITY & OH&S POLICY	10/02/26

Rev.	Effective Date	Description of the revised points	Edited by RSQ Date	Approved by GM Date
00	24/01/25	First issue as attachment for details on the quality policy		
01	10/02/26	Revision for integration with ISO 45001	10/2/26 <i>Polonius</i>	10-2-26 <i>[Signature]</i>

The General Management of LLL considers it essential to define, promote and keep updated an integrated company policy that includes Quality and Health and Safety at Work, consistent with the purposes of the organization, i.e. the production, through mechanical machining according to the customer's design, of medical devices and other products, such as small turned metal parts in steel and light alloys for high precision uses.



By the will of the Management, the production, quality and safety standard is kept constantly high, regardless of the type of product supplied — semi-finished or finished, medical device or component intended for other application areas. With this in mind, the Quality Manual, procedures and operating instructions are drawn up, with specific exceptions, always considering the quality level required for a medical device, which represents the highest degree of quality required.

The Management also recognizes the importance of establishing, implementing and maintaining:

- a Quality Management System (QMS) compliant with ISO 9001, ISO 13485 and 21 CFR 820 (USA);
- an Occupational Health and Safety Management System compliant with ISO 45001 (SGSSL);
- as fundamental tools to ensure the control of business processes and the continuous improvement of performance.
- In particular, through these systems, the Management undertakes to:
 - provide objective evidence of the company's ability to meet all applicable requirements, whether explicit, implicit or regulatory;
 - guarantee the safety of people and the protection of the environment, providing safe and healthy workplaces in order to prevent accidents and occupational diseases;
 - assessing the impact of climate change on business activities;
 - to spread awareness of the importance of customer satisfaction and safety at work at all organizational levels;
 - ensure compliance with legal and other applicable requirements;
 - integrate management system requirements into business processes;
 - provide adequate resources for the operation and improvement of systems;
 - promote and ensure continuous improvement through planned audits, corrective and improvement actions;
 - constantly develop company resources, both human — promoting professional growth, safety and ethics — and technical and environmental;
 - make workers aware of the risks associated with their activities and their active role in the management system;
 - promote effective communication on the importance of compliance with management system requirements;
 - guide and support all staff to actively contribute to the effectiveness of the systems;
 - encourage the reporting of accidents, dangers and risk situations, including potential ones, ensuring the absence of retaliation.

To achieve these objectives, it is essential that all personnel strictly respect and apply the documentation of the management systems, as unauthorized deviations are not allowed. Internal audits are aimed not only at identifying and resolving non-conformities, but also at continuously improving the effectiveness of the systems themselves.

Particular attention is paid to the prevention and management of non-conformities and risks at all stages of

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the production cycle, in order to guarantee both the quality of the product and the health and safety of workers. Customer satisfaction is a key indicator of company performance and is constantly monitored, pursuing continuous improvement also through careful and constructive management of complaints.

The LLL Management has also defined a Company Safety Organization Chart, in which the responsibilities, authorities and tasks of the various functions are clearly identified. This organization chart is constantly updated and disseminated at all levels of the organization.

Consultation and active participation of workers are considered essential elements for the effectiveness of the OHSMS. All staff are therefore involved and empowered to take care not only of their own health and safety, but also of that of others, and are put in a position to promptly report any dangerous or risky situations, without fear of retaliation or disciplinary measures.

As part of the Group's growth strategy, the acquisition in 2018 of a production unit based in the Republic of San Marino contributed to the expansion of the customer portfolio and the acquisition of new skills, technologies and production capacities, with positive effects especially in the implantable medical device sector.

The company's growth, entry into the US market and the entry into force of Regulation (EU) 2017/745 on medical devices have made it necessary to adapt management systems to European regulations, FDA provisions and Good Manufacturing Practices (GMP). To this end, starting from May 2021, a process of revision of the quality system and related procedures was launched.

This Integrated Policy is the reference for defining and verifying the company's objectives, in particular in the context of the Periodic Management Review. Its adequacy, timeliness and correct application are systematically checked during these reviews.

The LLL Management is committed to ensuring that this Policy, an integral part of the Quality Manual, is disseminated, understood and applied at all levels of the organization. The Quality System Manager (QSR) has the authority and independence necessary to identify, report and resolve any critical issues relating to the implementation of the management systems and the Policy itself.