Rev.	Effective Date	Description of the revised points	Edited by RSQ Date	Approved by GM Date
0	30/06/03	Issued for adaptation and extension to UNI EN ISO 9001:2000		
1	30/11/09	Issued for adaptation to UNI EN ISO 9001:2008		
2	02/05/16	Issued for adaptation to UNI EN ISO 13485:2012		
3	06/10/16	Updated due to recommendations and verbal contributions by ICIM		
4	21/06/17	Annual update		
5	15/01/18	Update to UNI EN ISO 9001:2015 and 13485:2016		
6	18/01/19	Update for LSM-MED acquisition		
7	10/05/21	Update to 21 CFR 820 US current GMP et alter		
8	08/02/23	Update of harmonized standard EN ISO 13485:2016 + A11:2021 under EU Regulation UE 2017/745 and removal of year indication from standard reference	8/2/23	08-02-23

LLL General Management believes that it must define, promote, and keep updated a Quality Policy that is appropriate for the purposes of its organization, that is, the production, through machining based on the customer's drawing of class I, IIa, and IIb medical devices and other products, such as small lathed metal parts made of steel and light alloys for high-precision applications.

By the intention of LLL General Management, the production and quality standard is always maintained at a high level regardless of the product supplied, whether a semi-finished product / finished product or a medical device or other small part for different application areas. Therefore, the quality manual, the procedures, and the operating instructions, except for any necessary exceptions, are always drafted with a view to supplying a part as if it were a medical device, which represents the highest level of quality that may be required.

LLL's General Management also recognizes and promotes the need to establish, apply, and keep constantly updated a Quality Management System that is documented and compliant with the requirements of standards EN ISO 9001, *EN ISO 13485+A11 and 21 CFR 820 US* standards, as a means:

- to give objective proof of the company's ability to supply products that fully meet all explicit and/or implicit and/or legal and regulatory product requirements;
- to ensure the safety of people and environmental protection;
- to spread awareness throughout the company of the importance of fulfilling the customer's requirements and to make this a corporate priority of the first order;
- to promote and ensure the commitment to implement continual improvement through a planned system of checks on the status of the QMS itself and corrective and improvement actions;
- to constantly promote the search for objectives to improve corporate and human resources, encouraging the continual improvement of professionalism and ensuring safety in their activities and ethics in work relationships, as well as technical resources and environmental protection.

In order to implement the framework of the aforementioned general objectives in the best possible way, it is fundamentally important that all Company personnel observe and apply the documentation comprising the QMS, since deviations from their contents are not permitted; the planned system of internal audits has as its purpose and objective the elimination of any non-conformity as well as the search for improvement of the effectiveness of the QMS itself.

In addition, particular attention must be paid to preventing and/or correcting situations of non-conformity at all stages of the product realization cycle related to the quality of the products.

Customer satisfaction is a fundamental element of reference, and to this end its improvement must be objectively monitored and pursued; the reduction of customer dissatisfaction is another fundamentally important aspect, also with careful, proper, and constructive handling of any complaints.

The acquisition in 2018 of a production unit, located in San Marino, is consistent with the Corporate strategy which aims to extend the customer portfolio, acquiring know how, innovative technologies and productive force with positive impact on the implantable medical devices market in general.

With the increasing of the company, the acquisition of new customers operating in the US market, and the entry into force of the new European Regulation on Medical Devices 2017/745, it has been mandatory to be comply to the latter and to FDA and GMP regulations. For this reason, starting at May 2021a revision of Quality System and company procedures has started.

The Quality Policy as defined above is to be considered the element of reference for establishing and verifying the quality goals and in particular what has been analyzed and decided during the periodic Management Review (Section 5.6 of the QAM); the continued relevance and adequacy of the Policy, as well as its implementation, will be subject to evaluation during the Reviews.

LLL's Management undertakes to ensure that this document, in addition to being an integral part of the QAM, is disseminated, understood, and implemented by all possible means by the entire company; the QSM has the necessary authority and freedom to identify, report, and eliminate problems concerning the correct implementation of the QMS and the Quality Policy.

REFERENCES

Standard	EN ISO 9001, Section 5., Quality Policy
Standard	*EN ISO 13485+A11, Section 5.3, Quality Policy*
Standard	*21 CFR 820, § 820.20 (a) Quality policy*
MDR 2017/745	

QAM Section 5.6 - Management Review