The Management of **VISIA LAB** considers it essential, for the strategic development of the company, to establish and maintain a ***Quality Management System*** in compliance with mandatory national and international regulations and technical regulations concerning IVDs and active medical devices, where applicable. In particular, it undertakes to operate in substantial accordance with the UNI CEI EN ISO 13485:2021 standard to the MDSAP program relating to the countries of marketing, to Regulation (EU) 2017/746, as well as to the applicable international GMP requirements and the regulations applicable in the countries in which the products are marketed.

The Organization has established the following **strategic objectives**:

1. ***ENSURE CUSTOMER SATISFACTION*** by:
   a. Customer-oriented organization and processes
   b. Identification and control of customer requirements, both explicit and implicit
   c. Provision of technologically advanced, safe and effective IVD devices
   d. Provision of design, manufacturing and support services for IVDs or active medical devices
   e. Maintaining awareness within the Organization on the importance of meeting the customer's needs

2. ***GUARANTEE AND IMPROVE THE CORPORATE IMAGE*** through:
   a. The provision of high quality products and services
   b. Timeliness of action and transparency and precision in the exchange of information

3. ***ENSURING MUTUALLY BENEFICIAL RELATIONSHIPS WITH CUSTOMERS AND SUPPLIERS***

4. ***GUARANTEE THE RESOURCES AND MEANS NECESSARY FOR THE PROPER FUNCTIONING OF THE ORGANIZATION.***

5. ***ENSURE THE ENHANCEMENT OF HUMAN RESOURCES*** through:
   a. Increased skills
   b. Involvement, motivation and awareness of all collaborators so that each one ensures the highest level of quality in the execution of the process phases pertaining to him/her.
   c. Staff education and training as strategic activities and essential conditions for achieving continuous improvement within the organization
   d. Growth and maintenance of company knowledge in relation to technological development
   e. Adaptation of the professionalism of employees to the tasks deriving from the policies and objectives defined by the Management

6. ***ENSURE THE EFFICIENCY OF BUSINESS PROCESSES***, also in terms of controlling operating costs, through:
   a. Process monitoring based on measurable and appropriate indicators
   b. Periodic review of process performance
   c. The implementation of correction and improvement actions based on facts
   d. Attention to the prevention of non-conformities in processes;
   e. Process optimization while maintaining a high level of quality and efficiency, ensuring the right quality/price ratio for the customer

7. ***ENSURE THE EFFICIENCY OF THE EXCHANGE OF INFORMATION WITHIN THE ORGANIZATION AND EXTERNALLY*** (customers and suppliers) through the dissemination of appropriate guidelines and procedures and the provision of suitable technological tools.

8. ***ENSURE THE MAINTENANCE OF THE EFFECTIVENESS OF THE QUALITY MANAGEMENT SYSTEM***. Activate an adequate self-control system that allows to measure activities, neutralize problems and provide the Management with suitable elements to carry out the reviews.

9. ***ENSURE THE CONTINUOUS IMPROVEMENT OF THE QUALITY MANAGEMENT SYSTEM*** by adopting a systemic approach to the management of the organization based on process-based management of operational and support activities.
10. ***TO ENSURE, FOR THE DEVICES PRODUCED, THE HIGHEST POSSIBLE STANDARD OF SAFETY AND EFFICACY,*** in particular through a risk control process that ensures the reduction to an acceptable level of reasonably foreseeable risks through the evaluation of the clinical experience gained and the periodic review of the risk assessment.
11. ***ENSURE THAT APPLICABLE REGULATORY REQUIREMENTS ARE DETERMINED AND COMPLIED WITH***
12. ***REDUCTION OF NON-QUALITY COSTS***;

The **Quality Manual**, **(MdQ),** to which this document belongs, describes in detail all the actions and checks that are carried out to achieve the objectives that the company aims to achieve in an adequate and satisfactory manner.

The Management is committed to spread and disseminating the issue of Quality among its operational staff, through awareness and periodic training.

Each collaborator is required to receive and implement the Quality Policy defined by the Management, to transfer it to their activities and to verify the results.

At least annually, a review of the Quality Management System is carried out, through all the tools provided for by the reference legislation, to verify its efficiency and effectiveness.

The Management, therefore, issues and disseminates a document every year in which it provides specific guidelines and objectives and the corresponding commitments for the year indicated.

Date: 03/06/2026

The Management

Marco Meoni