

Quality policy

Edition:00 - Revision:03

Date of issue. 26 May 2021

The Management of **FB VISION SpA**, manufacturer of medical devices pursuant to Directive **93/42/EEC** and subsequent amendments and by **EU Regulation 2017/745**, is particularly sensitive to market needs and considers the Customer's feedback of crucial importance by implementing a correct quality assurance and control policy. In particular, the Company's Policy is as follows:

Goals and directives

- meet the requirements of It. Legislative Decree 24/02/97, no. 46 and subsequent amendments, Dir. 93/42/CEE and subsequent amendments and (EU) Reg. 2017/745;
- compliance with current, mandatory Regulations, common specifications, and MDCG;
- obtain and maintain the certification of the Quality Management System according to ISO Standards 9001 and ISO 13485 over time;
- quality and safety of the manufactured and marketed product;
- periodic assessments aimed at identifying the degree of Customer satisfaction, in relation to the services/products manufactured and marketed;
- prevention rather than a posteriori elimination of defects;
- taking responsibility for their own work;
- evaluate the Customer's feedback for the product/service provided;
- periodic assessments of new Customer needs;
- personnel training regarding the Quality System procedures, in compliance with current regulations;
- keep evidence of the activities carried out available to customers, upon request;
- improvements necessary to maintain the effectiveness of the Quality Management System and its processes;
- product safety;
- satisfy the Customer for the product/service provided.



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To implement this Policy, the Management undertakes continuous market research for the improvement of its products and services.

This policy will make a considerable contribution to guaranteeing the reliability, professionalism and efficiency that have always characterised the Company's activities. To this end, the Company will be committed to assisting all its staff in carrying out the Quality System Procedures correctly, training them appropriately and stimulating them to improve the quality required.

This goal can only be achieved with the full commitment of each one of us.

