



## QUALITY POLICY

The PIC DENTAL Quality Policy is aimed at guaranteeing the correct Design, Manufacturing and Marketing of dental impression materials and marketing of dental accessories, in such a way that they satisfy the expectations of our clients and users, our contractual obligations, as well as the applicable legal and regulatory requirements and commitment to continuous improvement.

To achieve this objective, the company's action strategy is based on the following principles and commitments:

- Guarantee excellence in the quality of execution of PIC TRANSFER.
- Understand and satisfy the needs and requirements of our clients.
- Understand and comply with our contractual obligations.
- Maintain a Quality Management System effectively.
- Ensure compliance with applicable Legal and Regulatory requirements.

The General Management assumes the responsibility of defining, implementing and maintaining this Quality Policy, for which it has based the QUALITY MANUAL and its Quality Management System in accordance with the requirements of:

- The current version of the EN ISO 13485:2016/A11:2021 standard.
- European Regulation EU 2017/745 and its modification by Regulation 2020/561 on medical devices
- 21 CFR 820 Quality Management System Regulations. FDA, USA.
- RD 192/2023.

The effectiveness of the PIC DENTAL Quality Management System depends on the unconditional support of all our employees, which is why the staff endorses the concern for Quality, understanding the importance of the task they perform and that the sum of all of them makes it possible to achieve the objectives.

The Quality Management will be under the direct supervision of the General Management of the Company, in order to be totally independent from the other departments. Your access to the management spheres will allow you to suggest the implementation of any procedures, reviews or Corrective Actions you consider necessary for compliance with the Quality Management System.

The General Management of PIC DENTAL will establish the necessary measures to ensure that the Quality Policy is disseminated in all areas of the Company, committing to it being understood, applied, reviewed and updated.

The General Management of PIC DENTAL defines the specific objectives of the company and its key elements to comply with what is defined in its Quality policy, assigning to each department the necessary authority and responsibility, making available the possible Human and Technical Resources. for the fulfillment of the objectives. In accordance with 21 CFR 820.20.

Director General

IDITEC NORTH WEST S.L.

19-10-2023

Rev.:02