

QUALITY POLICY

The Management of ORTHOAPNEA ensures that the quality policy:

- Is adequate for the purpose of the organization, through its annual inspection.
- Includes a commitment to comply with the legislation applicable to the ORTHOAPNEA products and services to meet the requirements of standard UNE-EN ISO 13485: 2016 and regulations to maintain the effectiveness of SGC.
- Provides a framework for establishing and reviewing quality objectives.
- Is communicated and understood within the organization.
- Is revised for its continuous adaptation.

ORTHOAPNEA, believes that the development of the Quality Management System and its use in an appropriate way will translate in a valuable tool for the achievement of the business objectives, since as premises of it should serve to increase our efficacy, our efficiency and improve continuously, raising the degree of satisfaction of our customers.

For this purpose this Quality Policy will be linked to the evolution of our activities and to the exercise of our functions, assuming that the optimal performance of the same must be promoted and obtained thanks to the planning of the quality objectives and execution of the programmed actions to achieve it. I commit myself to provide the resources planned for this purpose and to monitor the progress of these plans, which will be annually communicated together with this **QUALITY POLICY**, so that the whole organization is aware of them and collaborates within their possibilities and their responsibilities.

The OrthoApnea Company designs, commercializes and distributes the **ORTHOAPNEA KIT** which contains essential elements for the elaboration of the final device by the prosthetist. These elements, that are part of the product **ORTHOAPNEA KIT**, are Class I medical devices.

These plans will be reviewed by the Management in the annual that will be carried out on the system efficacy and the client's satisfaction degree.

Date: February 2015

Signature: OrthoApnea Management