


ORTHOAPNEA, S.L.
QUALITY MANUAL

CHAPTER : 5.	TITLE : MANAGEMENT RESPONSIBILITY		
SECTION: 3	TITLE: QUALITY POLICY		
 Responsible for Quality management	Review : 2	Page: 1 of 1	Date Effective : 16/02/2015

REFERENCES:

- PA-42-1 "REVIEW OF THE SYSTEM EFFECTIVENESS BY THE MANAGEMENT, QUALITY OBJECTIVES. CONTINUOUS IMPROVEMENT".

THE QUALITY POLICY

The management of ORTHOAPNEA ensures the quality policy

- o Is appropriate to the purpose of the organization.
- o Includes a commitment to comply with the law applicable to the ORTHOAPNEA products and services in order to meet the requirements of the UNE-EN ISO 13485:2013 policy (see Quality Manual, chapter 1, section 2; and chapter 2, section 1) and to maintain the effectiveness of the QMS.
- o Provides a reference framework for establishing and reviewing the quality objectives.
- o It is communicated and understood within the organization.
- o Is reviewed for its continuous adequacy.

ORTHOAPNEA believes that the development of the Quality Management System and its use in a suitable manner will be transformed into a valuable tool for the achievement of business objectives, since premises of the system should serve to increase our effectiveness, and to improve efficiency continuously, raising in the same manner the degree of satisfaction of our customers.

Therefore, this Quality Policy will be linked to the evolution of our activities and the exercise of our functions, assuming that the optimal performance of them should be promoted and pursued thanks to the planning of the quality objectives and execution of the actions planned to achieve it, since by these lines I am committed to provide the resources allocated to these objectives and to make a follow up on the progress of these plans, which will be reported annually and attached to this quality policy, so that the entire organization is aware of the them and collaborates to the extent of its capabilities and responsibilities.

The Orthoapnea company designs, markets and distributes Orthoapnea Kit which contains the elements necessary for the preparation of the final device by the prosthetic. These elements are part of the ORTHOAPNEA KIT product which belongs to health products of Class I.

These plans will be reviewed by the management as sets the PA-42-1, incorporated in the annual review the management will conduct on the effectiveness of the system and the degree of customer satisfaction.

REASONS FOR THE REVIEW