

Quality Policy

It is the policy of SmartCardia to develop, manufacture and market safe and effective products to applicable specifications that meet national and International Standards and Regulatory Requirements.

To meet customers satisfaction without contradicting Standard and Regulatory Requirements

To continuously improve the Quality Management System.

The Company's top management considers itself a leader that is involved in all aspects of this policy's implementation, and through its Quality Representative is solely responsible for the quality of its product, utilizing personal commitment of all its employees.

SmartCardia S.A. provides the appropriate human and financial resources as well as the necessary equipment to carry out the design, production, technical support, the distribution of the product(s) and finally to achieve its objectives.

SmartCardia S.A. has developed a Quality Management System described in this Quality Manual, and the associated procedures and work instructions to be compliant to ISO 9001:2008 and to ISO 13485:2012 as a result of the Annex B of ISO13485:2012,¹, as well as the Council Directive MDD 93/42/EEC for Medical Devices (consolidated with Directive 2007/47/EC),the most recent consolidated version of Part 1, Canadian Medical Device Regulations (SOR/98-282). Regulatory requirements always take priority over customer or other requirements.

This Quality Manual has been developed to cover also the essential requirements of ISO 9001:2015 and to ISO 13485:2016.

The Quality System adheres to the major principles of Good Manufacturing Practice (GMP) and the Good Distribution Practice (GDP) for Medical Devices and selected excerpts form the EU GDP for Medicinal Products in its daily function and procedures.

SmartCardia developed and implemented a quality management system to demonstrate its ability to consistently provide product that meets customer and regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity.

SmartCardia S.A. has been certified as per CE for its product SmartWearable does.

President

Date: 25th November 2017

¹ ISO13485; Annex B; Correspondence between ISO 13485:2012 and ISO 9001:2008