Quality Policy of SmartCardia

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.

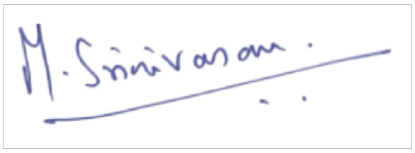
SmartCardia S.A. provides the appropriate human and financial resources as well as the necessary equipment to carry out the design, production, technical support, the distribution of the product(s) and finally to achieve its objectives.

SmartCardia S.A. has developed a Quality Management System to be complaint to ISO 9001:2015 and to ISO 13485:2016 as a result of the Annex B of ISO13485:2016, [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.

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.

THE MANAGEMENT



Srinivasan Murali

President

Lausanne, 30.09.2018

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