micrel
Medical Devices

QUALITY POLICY

Athens, 12/01/2018

Micrel Medical Devices S.A. develops, manufactures and markets medical devices and is committed to meeting customer and regulatory requirements by maintaining an effective quality management system.

We are committed to fully satisfy the needs of our customers by delivering high quality medical devices, solutions and services by applying a quality management system compliant with ISO 9001:2015, ISO 13485:2016, ISO 14971:2012, Directive 93/42/EEC as amended by the Council Directive 2007/47/EC, CMDR SOR/98-282, FDA 21 CFR 820, as well as numerous other medical devices related standards and directives which shall be followed meticulously.

We maintain our quality system by managing product risk and achieving objectives related to:

1. Customer satisfaction
2. Product development and improvement
3. Quality system improvement, Process effectiveness and efficiency & Regulatory compliance
4. Supplier quality assurance and performance
5. Resources and Personnel training and competence

Quality Policy is communicated and well known to all employees and stakeholders. Top Management and the Quality Assurance Department introduce and train all personnel to the necessary aspects of the Quality Management System. Negation or ignorance of the Quality System is not accepted.

Our Quality Policy, Quality Management System and Quality Objectives are reviewed on a regular basis by Top Management, leading to improvements, changes and the definition of new quality goals.

The Top Management of Micrel is declaring its commitment to quality on every aspect of company's activities and continuous improvement.

ALEXANDRE TSOUKALIS

Managing & Technical Director

NIKITAS MACHLIS

Chairman

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