

QUALITY POLICY

TH.KAZANTZIDIS SA - MEDIPAC, established in the Kilkis Industrial Area, is a manufacturing company of sterile surgical sutures. TH.KAZANTZIDIS SA - MEDIPAC is also responsible for the disposal of the above medical devices.

The basic principle and commitment of TH.KAZANTZIDIS SA - MEDIPAC, as well as the philosophy of each of its executives, is to provide its clients with services that fully meet or even exceed their contractual requirements, comply with the relevant legislative and regulatory requirements and achieve the goals set by the company for each project it undertakes.

To accomplish the above, the Management of TH.KAZANTZIDIS SA - MEDIPAC :

1. Has adopted a Quality Management System in accordance with International Standards ISO 9001:2015, ISO 13485:2016 and ΔΥ8/1348/04, which it applies to the whole company and to all activities that impact on the quality of its products and the satisfaction of its customers.
2. Has adopted the regulation 2017/745 on medical devices. This regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. Key elements of the existing regulatory approach are compliance Evaluation procedures, clinical investigations and clinical evaluation, vigilance and market surveillance have been significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices have introduced, to improve health and safety.
3. Evaluation procedures, clinical investigations and clinical evaluation, vigilance and market surveillance have been significantly strengthened, while provisions ensuring transparency and traceability of medical devices should:
 - improve health and safety.
 - Review and continuously improves the features of its products, where feasible, as well as the effectiveness of its processes and, by extension, of the entire QMS.
 - Set measurable objectives for quality at corporate level, at operational level of Departments and/or Processes, as well as at the product level. These objectives are established and evaluated as to their degree of achievement in the context of the QMS Review by the company's Senior Management.

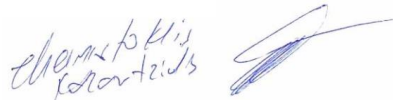
- Harness the data and information for the achievement of these objectives.
- Provide the necessary resources for the unimpeded, efficient and effective operation of every company Department.
- Invest in the continuous training, updating and instruction of its executives in order to ensure Quality in all their activities.
- Identify and deals with the potential threats and harnesses the opportunities that may affect product compliance.
- Monitor, measures and evaluates critical parameters and processes, in order to ensure Quality.
- Be available to interested parties.
- Set targets at each level based on customer satisfaction, compliance with regulatory requirements and having ultimate aim of reducing risk as low as possible.

Adopting the principle of continuous improvement, TH.KAZANTZIDIS SA - MEDIPAC recognizes and rewards teamwork and individual effort, invests in People and respects the Customer.

Themistoklis Kazantzidis

CEO

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