Quality Policy of BIOPIX-T

Our mission at BIOPIX-T, is:

- ***To offer safe portable In-diagnostic medical devices (Instruments and kits) to every potential end-user, regardless of financial status, geographical location and training.***

- ***Doctors, healthcare providers and patients in both the developed and developing countries will benefit equally from our technologies, which intends to alleviate personal suffering and control disease outbreaks.***

This will be accomplished through employee and subcontractor's involvement and ongoing education to ensure continuous improvement of our processes.

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

To meet customers safety and 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.

BIOPIX-T 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.

- BIOPIX-T has developed a Quality Management System described in this Quality Manual, and the associated procedures and work instructions to be complied as per EN ISO 13485:2016 as a result of the Annex B of ISO13485:2016, [1], as well as the Council Directive IVDD 98/79/EEC *Annex and European Regulation IVDR 2017/746*, SAHPRA Medical Devices And IVDs Essential Principles Of Safety & Performance Nov. 19, v2 and TMDA-Guidelines on Submission of Documentation for Registration of In Vitro Diagnostic Devices, edition 3rd, April 2020 for in-Vitro Diagnostics Medical Devices. Regulatory requirements always take priority over customer or other requirements.

The Quality System adheres (when and if this required) to the major principles of Good Manufacturing Practice (GMP) and the Good Distribution Practice (GDP) for Medical Devices and selected excerpts from the new EU GDPR for Sensitive Medical Data in its daily function and procedures.

BIOPIX-T 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.

[1] ISO13485; Annex B; Correspondence between ISO 13485:2016 and ISO 9001:2015

BIOPIX-T does not intend to release and sell any of its product(s) into the European market before the official clearance and relevant approval of its products by the National Competent Authority or before issuing CE mark by a Notified Body, respectively.

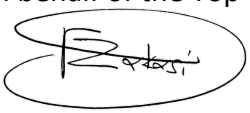
BIOPIX-T does not intend to release and sell any of its product(s) into the S. African and Tanzanian market before the official registry and relevant approval of its products by the respective National Competent Authority.

This quality policy is communicated to all employees as part of their training, with the intent of providing a clear, common understanding, directly applicable to their work.

To maintain a clear communication, Quality Policy is displayed on the Quality Manual and throughout the organization as well as to the company's website.

It will also be reviewed at least once per year by the management to confirm suitability adequacy of the organization.

On behalf of the Top Management



Ioannis Zakasi
Quality Management Representative