The Quality Policy of the company “PROIGMENES OFTHALMIKES TECHNOLOGIES EPE”, operating under the trade name “OPTOTECH LTD”, for the activity: “Design, Development, Production, Publishing, Installation and Technical Support of Standalone Medical Device Software Based on Eye Movement Recording”, focuses on:

1. The design, development, production, and support of safe, reliable, and high-quality medical device software that meets its intended purpose and the specified safety and performance requirements.

2. Meeting the requirements of customers and product users, with particular emphasis on protecting the safety of patients and other individuals affected by its use.

3. Continuous compliance with applicable legislative and regulatory requirements for medical devices, particularly Regulation (EU) 2017/745, the requirements of ISO 13485:2016, and personal data protection legislation.

4. Operating the Company in accordance with the principles of equality, meritocracy, and non-discrimination, while ensuring an appropriate working environment that promotes responsibility, collaboration, and professional competence among employees.

To achieve the above, Management is committed to:

1. Ensuring compliance with the applicable requirements of ISO 13485:2016, Regulation (EU) 2017/745, and relevant legislation, as well as the effective implementation and maintenance of the Quality Management System (QMS).

2. Ensuring the quality, safety, and performance of medical device software through controlled design, development, production, verification, validation, and change management activities.

3. Implementing systematic risk management throughout the product lifecycle, prioritizing patient and user safety and maintaining an acceptable benefit-risk ratio.

4. Providing the necessary resources, appropriate personnel training and competence, and clearly defining roles and responsibilities.

5. Ensuring that customer and user requirements are met through feedback evaluation, complaint handling, clinical evaluation, and post-market surveillance of the product, including vigilance activities and required regulatory reporting.

6. Establishing and monitoring measurable quality objectives aligned with the Quality Policy and evaluating their achievement through appropriate performance indicators.

7. Reviewing the suitability, adequacy, and effectiveness of the Quality Management System at planned intervals and making the necessary decisions to maintain compliance and improve processes and the product. 8. Ensuring that the Quality Policy is communicated to, understood, and implemented by personnel, made available to relevant interested parties where required, and reviewed for its continuing suitability.

Quality Management System

The central focus of the Quality Management System is the safety and performance of medical device software, with particular emphasis on user needs, patient protection, and ensuring that the product complies with its intended purpose. The main objectives are:

1. To develop and make available medical device software that meets specified quality, safety, and performance requirements.

2. To leverage scientific knowledge and technological innovation in the field of Ophthalmology to develop reliable and appropriately documented solutions.

3. To meet agreed customer requirements and provide effective technical support to product users.

4. To promote scientific research and utilize its findings in the development and evaluation of medical device software.

5. To maintain and sustainably develop the Company's business activities while ensuring regulatory compliance and product quality.

6. To ensure that all personnel consistently implement the approved procedures, work instructions, and other requirements of the Quality Management System.

7. To promptly identify and address nonconformities, implement effective corrective and preventive actions, and utilize monitoring results to improve processes.

The continuous effort to improve product quality and the services provided, compliance with applicable requirements, and maintenance of the effectiveness of the Quality Management System constitute a fundamental commitment of Management and a responsibility of every Company employee.