## **RITM OKB ZAO QUALITY POLICY**

The strategic Quality Management goal of RITM OKB ZAO is the maximal fulfillment of expectations and requirements of the customers that is reached by development, manufacturing, and sales of competitive high-quality medical devices and diagnostic systems.

**The main instrument** for achieving this goal is the Quality Management System that is based on the process approach and risk-oriented thinking, and complies with the requirements of ISO 9001:2015, ISO 13485:2016, and Medical Device Regulations (EC) 2017/745.

## The goal is achieved by solving the following problems:

- improving the quality and customer features of the products developed and manufactured by the Company;

- systematic analysis of the current and perspective customer demands and expectations, objective assessment of satisfaction with the Company's products;

- improving the quality and reliability of the service;

- increasing the volume of sales and expanding the product markets;

- creating strong positive Company image at the Russian and foreign markets;

- developing and improving the technical and methodical aspects of the matters related to the developed and manufactured products, organizing clinical and other studies;

- building mutually beneficial relationships with the suppliers and subcontractors that ensure the demanded quality of the purchased products and services;

- creating healthy social and psychological climate, technical and organizational environment that provides for realization of professional and creative potential of every employee, involving the staff into the process of the continuous improvement of the products' quality, systematic education in the sphere of Quality Management;

- forming the stable manufacturing of the Company and strong financial status of all employees;

- strict following the requirements of the internal and external normative documents, as well as the laws of the Russian Federation and other countries where the Company's products are sold.

## The Management of RITM OKB ZAO takes on the obligation to:

inform all its employees regarding the Quality Policy and ensure its understanding;

control the process of obtaining the planned results;

• make the Company's QMS comply with the requirements of ISO 9001:2015, ISO 13485:2016, Medical Device Regulations (EC) 2017/745 and ensure its continuous improvement;

• manage all resources that are necessary for effective work of the Company and make them available for the Quality Management System.

**General Director** 

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Yury Starovoytov 26.05.2021 г.