

ORTHOMED E® | QUALITY POLICY

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Welcome to **ORTHOMED E®**, A leading orthopedic implants manufacturing company with rapidly expanding footprints all over the world. Within a short span of time since its launch, **ORTHOMED E®** has been able to carve out a leadership position in the countries where it has introduced its products due to its focus on satisfying the needs of Orthopedic Surgeons & Distribution Channel Partners, Quality of its products complying with worldwide standards, a wide and deep product portfolio serving its clientele. At **ORTHOMED E®**, the pursuit of quality is a key business focus. Our expertise in identifying the needs of our esteemed customers results in continuous development and launch of new products, benchmarking the products and processes against existing best practices and continuously expanding the product portfolio based on feedback from our customers.

ORTHOMED E® offers a wide spectrum of Implants i.e. (Intramedullary Nails, Bone Plates, Bone Screws, General Spine Systems, Dental Implants, Total Hip Prostheses, and Cement Restrictors) based on surgical implant materials. We have been awarded with EN ISO 13485:2016 and CE Mark for our precision implants.

ORTHOMED E® is committed to meeting customer, statutory, and regulatory requirements and increasing customer satisfaction through continual improvement of its products, services, and its Quality Management System. The organization is committed to maintaining the effectiveness of the Quality Management System by means of internal audits, management reviews and corrective action and preventive action procedures for any Quality Management System non-conformances.

OUR MISSION is enduring and declares,

- To continuously offer improved products and technologies to medical professionals to enable them to heal the patients faster and less hospitalization time.
- Develop strong linkages to Top Institutions and medical professionals in the field and bring to life their new concepts and ideas.
- Build good clinical databases to strongly back the products with clinical trials and extensive clinical experience.

OUR VISION guides every aspect of our business conduct and serves as a framework of our roadmap to growth and expansion.

- **People:** Be a great place to work and attract the best talent in the industry
- **Products:** World-class quality, extensive portfolio, novel technologies and new launches define our offerings.
- **Partners:** Nurture and grow a wide network of distribution channel partners, Orthopedic medical and para-medical professionals, and quality suppliers to offer an enduring value to all stakeholders.
- **Productivity:** Be highly effective, lean and fast-moving organization. Must leverage the collective strength of all stakeholders.
- **Profits:** Create long-term value for all stakeholders' while being mindful of our overall responsibilities.

MANUFACTURING FACILITIES

Our manufacturing facilities meet the stringent quality control criteria and constantly upgrade their infrastructure, systems and processes to keep pace with the latest regulatory norms.

We are committed to remain at the forefront of cutting edge in Orthopedics technology and our products are manufactured with avant-garde precision equipment. Our plants are equipped with fully automatic CNC Turning Machines, Horizontal Machining Centers, Automatic polishing machines, CNC thread milling machines, Ultrasonic cleaning machines, Laser marking machines etc. which ensure the quality and reliability of products through one- step manufacturing (from raw materials to finished products). The raw materials used in these finished products are procured from approved vendors, which are finalized after stringent vendor qualification audits.

STRUCTURE OF QUALITY SYSTEMS

In order to improve existing products and identify the need for new ones, we systematically monitor and evaluate the requirements of the customers. Effective quality assurance and after-sales procedures are a fundamental part of the organization's operations.

All personnel are obliged to comply with the jointly accepted operating principles defined in the quality system. Our management supervises compliance with these principles and is also responsible for developing the quality system. Management conducts annual monitoring of quality and environmental policy and checks whether targets have been reached. Management pays particular attention to personnel motivation and competence development. We have several procedures to ensure personnel's continued ability to meet the challenges set by the organization's operations.

QUALITY SYSTEM - ELEMENTS

- Quality Manual
- Standard Operating Procedures
- Reference Materials



The Regulation (EU) 2017/745 – Annex IX and EN ISO 13485:2016 quality system standards are applied in all production related activities and process operations. The quality system describes the flow of the processes so that everything related to customer service, the reliability and efficiency of operations, and environmental protection is defined to meet the requirements of the standard.

We employ Corrective Action and Preventive Action (CAPA) which is a fundamental management tool that is used in every quality system. The company has strong belief that this simple step by step process for completing and documenting corrective or preventive actions results in complete, well documented investigation and solution that will satisfy regulatory requirements and form the basis for an effective continuous improvement plan for the company. The ability to correct existing problems or implementing controls to prevent potential problems is essential for continued customer satisfaction and efficient business practice.

We use self-evaluation to develop our operations. Self-evaluation covers both evaluations of internal monitoring and the appropriateness of risk management. The principle of CAPA is employed as part of self- evaluation to ensure the effectiveness of our operations.

Authorized Signatory:

Name: Dr. Morris Fouad Tawadros

Position: CEO

Date: 24-Oct-2025

