

The Management of **PHYSIO MRI TECH S.L.** has implemented and maintains a Quality Management System (QMS) based on the requirements of **UNE-EN ISO 9001** and **UNE-EN ISO 13485**, as well as **Regulation (EU) 2017/745** and any other applicable legal, regulatory and standards requirements. The scope of the QMS comprises the following activities:

“Design and development, manufacturing, assembly, testing, distribution and installation of portable ultra-low-field magnetic resonance imaging (ULF-MRI) systems for diagnostic imaging.”

The Quality Policy is aimed at ensuring the quality, safety, performance and conformity of its medical devices, addressing the needs of **patients and users** and ensuring compliance with applicable requirements throughout the product life cycle. To this end, Management undertakes the following commitments:

- 1. Compliance with requirements.** Comply with applicable legal, regulatory, standards and contractual requirements, as well as the requirements established within the Quality Management System.
- 2. Product quality, safety and conformity.** Design, develop and manufacture safe, compliant medical devices suitable for their intended use, maintaining their quality, safety, performance and traceability throughout their life cycle.
- 3. Effectiveness and improvement of the Quality Management System.** Maintain the effectiveness of the Quality Management System and promote its continual improvement, providing the human, technical, material and organizational resources necessary for its proper operation, monitoring and development.
- 4. Risk management.** Apply a risk-based approach throughout the product life cycle and within QMS processes, identifying, evaluating, controlling and monitoring risks that may affect product quality, safety, performance or conformity.
- 5. Suppliers and external activities.** Ensure adequate control of suppliers, subcontractors, external services and materials that may influence product quality, safety, performance or conformity.
- 6. Monitoring, analysis and improvement.** Collect, analyze and use information obtained from monitoring products and processes, including feedback from patients and users, post-market surveillance, vigilance, nonconformities, audits and indicators, as a basis for decision-making and improvement of the product and the QMS.
- 7. Innovation.** Foster innovation in design, technology and processes, ensuring that it is developed within the framework of applicable quality, safety, performance, risk management and regulatory compliance requirements.
- 8. Personnel competence and awareness.** Promote personnel competence, training, awareness and participation, ensuring that each person understands their contribution to product quality, compliance with applicable requirements and the effectiveness of the QMS.
- 9. Quality objectives.** Establish and review measurable quality objectives consistent with this Policy, aimed at maintaining and improving the effectiveness of the QMS, product quality and safety, regulatory compliance and process improvement.
- 10. Environmental responsibility and use of resources.** Conduct the organization's activities making responsible use of resources and promoting pollution prevention, reduction and proper management of waste, and reduction of unnecessary consumption of raw materials, energy and water.

This Quality Policy shall be **communicated, understood and applied within the organization**, shall be available to relevant interested parties and shall be periodically reviewed to ensure its continued suitability to the purpose, context and strategy of **PHYSIO MRI TECH S.L.**, as well as to applicable requirements. Management undertakes to **maintain, implement and promote this Policy at all levels of the organization**.

Approved by:

CEO PHYSIO MRI TECH S.L.

Date and signature: 10/09/2026

