Management of PHYSIO MRI TECH S.L. has implemented and maintains a Quality Management System (QMS) based on the requirements of UNE-EN ISO 9001:2015 and UNE-EN ISO 13485:2016, "Quality management systems. Medical devices," as well as Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, and any other applicable legal, regulatory, and standards requirements. The QMS covers the following activities:

"Design, Development and Manufacturing of Medical Imaging Equipment
for Clinical Diagnosis (Traumatology and Physiology)"

To properly control this scope, the QMS includes the processes necessary to ensure the quality, safety, performance, traceability, and conformity of medical devices throughout their life cycle, including, where applicable, document management, record control, risk management, supplier and subcontractor control, production, packaging and labeling, installation, end-user training, post-market surveillance, vigilance, nonconformity management, corrective and preventive actions / CAPA, change management, internal audits, and management review.

The purpose of the QMS is to ensure the satisfaction of the customers and users of **PHYSIO MRI TECH S.L.**, compliance with customer-specified requirements, applicable legal and regulatory requirements, applicable reference standards, the organization's internal requirements, and any requirements necessary to ensure the safety, performance, and conformity of the medical devices manufactured.

To achieve this, Management of **PHYSIO MRI TECH S.L.** undertakes the following commitments:

- Comply with applicable legal, regulatory, standards, contractual, and customer requirements, as well as the requirements of the QMS in place.
- Ensure that the medical devices designed, developed, and manufactured by the organization maintain their safety, performance, traceability, and conformity throughout their life cycle.
- Maintain and continually improve the effectiveness of the QMS, providing the human, technical, material, and organizational resources necessary for its operation, monitoring, and improvement.
- Apply a risk-based approach to design, development, manufacturing, control, installation, intended use, post-market surveillance, vigilance, change management, and corrective and preventive actions / CAPA, in order to identify, assess, reduce, control, or mitigate the risks associated with the product and the processes.
- Effectively control the organization's activities, including subcontracted activities, critical suppliers, external services, and materials used, ensuring that they meet the established quality, safety, performance, traceability, and conformity requirements.
- Collect, analyze, and use the data generated by QMS processes, including production, installation, feedback, complaints, post-market surveillance, vigilance, risk management, nonconformities, CAPA, change management, suppliers, internal audits, and indicators, to support documented decision-making and improvement of the product and the system.
- Promote innovation in design, technology, and processes, while keeping such innovation within the framework of applicable safety, performance, risk management, quality, and regulatory compliance requirements.
- Promote personnel competence, training, awareness, and participation, ensuring that each person understands their contribution to product quality, regulatory compliance, and the effectiveness of the QMS.

- Establish, review, and maintain quality objectives consistent with this Policy, focused on improving the QMS, customer satisfaction, product safety, regulatory compliance, and process improvement.
- Conduct the organization's activities in an environmentally responsible manner, based on the principles of pollution prevention, waste reduction and recycling, conservation of raw materials, energy, and water, and responsible use of resources.

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

Approved by:
CEO PHYSIO MRI TECH S.L.
Date and signature: 05/05/2026