INBENTUS®
MEDICAL TECHNOLOGY

QUALITY POLICY

Date: 04.03.2024
Version: 1

The company **ICONIC SOLUTIONS BY MURCIA, SL (INBENTUS)**, in the field of *designing automatic mechanical ventilation systems*, aims to be a leader in its field. To this end we are committed to designing, manufacturing, and delivering medical devices that improve the health and well-being of patients worldwide. Our dedication to excellence is driven by a commitment to quality, safety, and efficacy in all aspects of our operations, from initial design through to post-market surveillance.

Commitment to Standards and Regulations:

We adhere to the highest industry standards and regulatory requirements to ensure the safety and reliability of our medical devices. This commitment is underscored by our strict compliance with, but not limited to:

- ISO 13485:2016 for Quality Management Systems, ensuring consistent design, development, production, installation, and delivery of medical devices that meet customer and regulatory requirements.
- EU Medical Device Regulation (MDR) 2017/745, which guides our operations within the European Union, emphasizing the safety and performance of our devices throughout their lifecycle.
- ISO 14971 for Application of Risk Management to Medical Devices, ensuring that risks associated with our medical devices are identified, evaluated, and controlled effectively.
- Other Applicable Regulations including, but not limited to, FDA regulations for the United States market, ensuring a global approach to quality and safety.

Risk Management:

Risk management is at the core of our Quality Management System. We proactively identify, assess, and mitigate risks throughout the product lifecycle, ensuring that our medical devices are safe for their intended use. Our comprehensive approach to risk management is aligned with the principles of ISO 14971, integrating risk analysis into product design, development, and post-market activities.

Post-Market Activities:

We are committed to monitoring the performance and safety of our medical devices post-market. This commitment involves:

- Vigilant post-market surveillance to detect any potential issues early.
- Swift and effective corrective actions, including recalls, if necessary, to ensure ongoing patient safety.

- Regular reporting to regulatory authorities in accordance with MDR 2017/745, FDA regulations, and other local requirements.

Continuous Improvement:

Continuous improvement is a cornerstone of our quality policy. We are dedicated to the ongoing enhancement of our Quality Management System, products, and processes through regular review, employee training, customer feedback, and performance metrics. Our goal is to exceed customer expectations and regulatory standards, fostering innovation and excellence in medical device manufacturing.

Employee Involvement:

Our employees are our most valuable asset in achieving our quality objectives. We foster a culture of quality, integrity, and accountability, where every team member is empowered and expected to contribute to our quality goals. Through continuous training and professional development, we ensure that our team remains at the forefront of industry standards and best practices.

Leadership Commitment:

The leadership team at INBENTUS is fully committed to upholding this Quality Policy, providing the resources necessary for its implementation, and ensuring that it is communicated, understood, implemented, and maintained at all levels of the organization. In addition to the above mentioned, INBENTUS will:

- Work with suppliers and subcontractors committed to the constant improvement of their product or service, ensuring both quality and competitive pricing.
- Have qualified employees who, along with appropriate technological resources, ensure the consistent quality of our services.
- Involve all members of the organization in the development and continuous improvement of the implemented system.
- Have the necessary tools to evaluate and understand the expectations of our customers and stakeholders, taking appropriate measures to achieve their full satisfaction with our work.
- Consider the evolution of the context applicable to the organization as input for system improvement.
- Ensure the protection of confidential information and the rights of customers.

The management will provide the necessary means for this Quality Policy to be understood, implemented, and kept up to date throughout the organization and stakeholders.

Review and Revision:

This Quality Policy will be reviewed annually and revised as necessary to reflect changes in regulatory requirements, customer expectations, and our strategic objectives.

Signed: Rafael Valverde
General Manager