Quality Policy

Shire Controls Limited recognises that quality, health & safety, and environmental management are integral to our operations and essential to achieving our business goals. We are committed to maintaining and continually improving a robust Quality Management System (QMS) that meets the requirements of ISO 9001:2015, ISO 13485:2016, and EU Medical Device Regulation (EU MDR) 2017/745.

We undertake the design & development, manufacturing, sale and supply of Medical Gas Alarms and Anaesthetic Gas Scavenging Systems and take full legal responsibility for the safety, performance, labelling, packaging, and regulatory compliance of our products prior to their placement on the market.

Shire Controls Limited Quality Policy calls for continuous improvement in its Quality Management activities according to the following principles:

- Compliance: Fulfil all applicable legal, regulatory, and statutory requirements, including those defined by ISO 9001, ISO 13485, and EU MDR 2017/745, with a strong emphasis on the General Safety and Performance Requirements (GSPRs) applicable to medical devices.
- Risk and Safety: Apply a risk-based approach to product development and lifecycle management to ensure that all products are safe, effective, and compliant. Implement appropriate post-market surveillance and vigilance processes to monitor product performance and take action where required.
- Continuous Improvement: Commit to the continual improvement of our QMS and quality processes by setting, monitoring, and reviewing measurable Quality Objectives. We ensure these objectives are communicated and understood across the organisation and to relevant interested parties.
- Customer Focus: Deliver high-quality, reliable and fully documented products that meet or exceed customer expectations and applicable regulatory requirements, ensuring high levels of customer satisfaction and confidence.
- People and Competence: Ensure all staff are trained, competent, and aware of their responsibilities in maintaining quality, safety, and regulatory compliance. Promote a culture of ownership and accountability throughout the organisation.
- Supplier and Partner Collaboration: Work closely with suppliers, contractors, and service providers to ensure that purchased components and services meet our strict quality and regulatory standards.
- Health, Safety & Environment: Maintain safe working environments for employees, customers, and end-users, and operate in a manner that minimises environmental impact.
- Management Commitment: Take a forward-looking approach to quality-related business decisions and allocate appropriate resources to maintain the effectiveness of the QMS and support long-term growth.

Signed.   Date.   14/05/2025

Greg Gardiner

Quality Manager

Shire Controls Ltd