

Quality Policy Statement

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Bolton Surgical Limited is an established manufacturer, supplier, distributor and repairer of re-usable surgical instruments for domestic and export markets.

It is the Policy of Bolton Surgical Limited to comply with its established Quality Management System (QMS) conforming to the requirements of EN ISO 13485:2016, UK Medical Device Regulations UK MDR 2002, relevant product related national and international standards, and NHS Labour Standards Assurance System through the effective implementation of the Company's Policies and Procedures. We will comply with the requirements of Medical Device Regulations MDR 2017/745 pending transition according to the needs of the business.

Bolton Surgical Ltd is committed to providing its' Customers with products of the highest quality and value for money, manufactured and supplied in accordance with all appropriate regulations and National/International standards whilst maintaining or exceeding Customer delivery requirements.

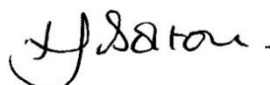
The Company shall conform to this Quality Policy according to the following principles:

We shall: -

- Comply with all applicable laws, regulations and standards.
- Follow a systematic risk-based approach to Quality Management and Regulatory Compliance.
- Ensure all Policies and procedures are effectively applied throughout the company.
- Work closely with our customers, supply chain and employees to ensure the highest product quality standards are maintained.
- Communicate the Company's quality, LSAS and regulatory requirements and objectives appropriately throughout the Company and supply chain and, review performance against these objectives in order to maintain the effectiveness of the QMS.
- Ensure due care and attention is applied to the safety of patients, end users, customers, suppliers, employees and others who come into contact with our products and services.
- Adopt a proactive, risk-based approach to continuous improvement of our QMS and, to business decisions that may have Quality, H&S, Environmental or other regulatory impacts.

In fulfilling this Policy, Senior Management shall ensure that all staff are appropriately trained in the needs and responsibilities associated with QMS, MDR and LSAS conformance, ensuring that this Quality Policy is understood, implemented, monitored and maintained with shared accountability at all levels within the organisation.

Approved By Signature:



Position: Managing Director

Bolton Surgical Limited

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