



POL06: QUALITY

POLICY

Rev: 05

HENLEYS MEDICAL SUPPLIES LTD.

Brownfields
Welwyn Garden City
Hertfordshire
AL7 1AN

01707 385226

www.henleysmed.com

1. Policy Statement

Henleys Medical Supplies Ltd is committed to providing all of our customers with products and services of an assured quality and standard. Our quality management system is certified to ISO 13485, and our certificate is available upon request.

As a company, we strive to maintain an effective and efficient quality assurance process, planned and developed in conjunction with all relevant staff, management, directors, and stakeholders. This is done through our company policies and procedures, as well as external contracts, regulations, standards, and codes of practice, which are designed to eliminate deficiencies and inaccuracies and to ensure high quality standards.

Targets are set for each coming year. These targets, and our policy, will be reviewed at regular intervals, with a view to maintain effectiveness, and, where possible, continually improve our performance. Company policies are available electronically at all times to internal employees, and externally upon request.

2. Policy

2.1. Scope

Henleys Medical Supplies is certified to BS EN ISO 13485, and we aim to maintain the effectiveness of our quality management system. We are committed to providing all of our customers with a professional and ethical service, and products of an assured quality and standard at an acceptable cost. We also comply with all relevant sections of the Medical Device Directive (93/42/EEC) as amended, and intend to comply with the Medical Device Regulation (EU/2017/745), and/or the Medical Device Regulation 2002 as amended, and/or the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020, as applicable in Great Britain.

2.2. Responsibilities

2.2.1. Managing Director

The Managing Director has overall responsibility for quality, and is supported in this role by the relevant team(s). The Managing Director also reports on quality assurance to the directors and stakeholders of Henleys Medical Supplies, together with the Regulatory & Compliance Department.

2.2.2. Senior Management/Managers

Senior Management are responsible for maintaining, reporting, and reviewing the quality assurance policy, together with the Regulatory & Compliance Department, at the Management Review Meeting.

Managers are responsible for ensuring that all employees understand and comply with the policy, objectives, systems, and associated documented processes.

2.2.3. Regulatory & Compliance Department

It is the responsibility of the Regulatory & Compliance Department to ensure that this policy remains relevant, and that all associated documented processes are effective at maintaining and improving the quality management system.

2.2.4. All Employees

All employees are required to understand their role in upholding the standards of this quality policy and the quality management system as a whole, and to ensure they work in compliance with all relevant documented procedures.

3. Review

This policy shall be maintained and reviewed by the Managing Director.



Danielle Henley, Managing Director

4. Revision History

Revision	Modified by	Date	Description of Change
01	Andy Cleveland	April 2015	Initial issue.
02	Andy Cleveland	April 2016	Annual review. Mobile numbers updated.
03	Vikki Patis	April 2017	Annual review.
04	Vikki Patis	April 2018	Annual review. New format.
05	Vikki Patis	December 2020	New format.