Quality Policy

Purpose

- The purpose of this policy is to set out Polyco Healthline's approach and commitment to quality and the quality management system.

- The policy supports the company's strategic direction and serves as a basis for establishing quality objectives.

Scope

This policy applies to all activities of Polyco Healthline Ltd and incorporates the principles of BS EN ISO 9001:2015+A1:2024 and BS EN ISO 13485:2016+A11:2021.

Definitions

For the purposes of this policy the following definitions apply.

- **Customer focus**
  The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

- **Infrastructure**
  Facilities, equipment and services needed for the operation of an organisation.

- **Management system**
  Set of interrelated or interacting elements of an organization to establish policies, objectives and processes to achieve those objectives.

- **Policy**
  Intentions and direction of an organization as formally expressed by its top management.

Policy Statement

Polyco Healthline Ltd provides both medical and non-medical protection and hygiene products, and services for the workplace and home. Our range includes re-usable and disposable gloves (sterile and non-sterile), surgical gloves, tourniquets, medical face masks and, polyethylene, pulp, paper and workwear products. We are committed to supply our products and services in a responsible manner, through the following:

- Understanding the requirements and needs of our customers, enabling us to provide a quality product and service.
- To monitor and measure customer satisfaction and service levels.
- To set business objectives, measure performance and take relevant corrective, preventive and improvement actions necessary.
- To ensure that adequate resources and infrastructure are in place to meet the business objectives.
- To maintain compliance to BS EN ISO 9001:2015+A1:2024 and BS EN ISO 13485:2016+A11:2021 and ensure the continued effectiveness of the quality management system.
- To maintain conformity to the directives and regulations that are relevant to our products and business, including but not limited to:
  - » Medical Devices Regulation (EU) 2017/745 (CE) and UK MDR 2002 (SI 2001 No 618 as amended) (UKCA).
  - » Personal Protective Equipment Regulation (EU) 2016/425 (CE), as brought into GB and amended (UKCA).
  - » Food Contact Regulation EU 1935/2004
- To maintain a training programme that ensures:
  - » This policy is understood, implemented and maintained at all levels within the company.
  - » The objectives of the business are supported.
  - » To where possible continually improve our products and services.
- To review the policy annually to ensure ongoing suitability.

With regards to PPE regulated products, this company undertakes to supply only safety equipment that fully complies with the standards and regulations and claims made relating to those products. Where appropriate, this company will maintain up to date technical files and associated documentation to ensure that regulatory compliance information can be supplied upon request. Where products are sourced from external organisations which hold technical files relating to the products being offered, this company will request confirmation that these files are current, complete, contain appropriate conformity assessment information and, where relevant, regulatory compliance certificates and will take all necessary steps to confirm the validity of the compliance documentation held by that external supplier in respect of the products being sourced.

Responsibilities

Board

The board and non-executive directors provide support and strategic direction for the company's quality management system.

Departmental Managers

Departmental managers are responsible for ensuring:

- Staff understand the processes, policies and procedures in each of their departments.
- That any quality management training (including induction and policy training) is recorded on the company Papaya platform.
- Educating and working with staff to ensure they understand how their role within the company supports the quality policy.

Technical Department

The technical department is responsible for:

- Management of the quality management system.
- Managing the management review.
- Data analysis and reporting of the company quality performance.
- Tracking and follow up of objective progress and management review actions.

Employees

Employees are required to comply with the company's policies and procedures as set out in their employment contract, handbook, and training plans.

Every member of staff impacts and supports meeting the quality policy.

Communication

This policy is communicated through the company shared drive/intranet, company website (www.polycohealthline.com), company notice boards, and forms part of the induction training programme; and will be made available to all interested parties.

Signature:		**Place of Issue:**	Bourne, PE10 0DN, UK
Name:	Brett Wakeley	**Issue Date:**	26/04/2026
Position:	Chief Commercial Officer	**Review Date:**	26/04/2026