

The Quality Policy drives the quality management system and aligns the purpose and strategic direction of the company.

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| 1 | Purpose | 1 |
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- 1.1 The purpose of this policy is to set out Polyco Healthline’s approach and commitment to quality and the quality management system.
- 1.2 The policy supports the company’s strategic direction and serves as a basis for establishing quality objectives.

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| 2 | Scope | 1 |
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- 2.1 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.

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| 3 | Definitions | 1 |
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For the purposes of this policy the following definitions apply.

- 3.1 **Customer focus**  
The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.
- 3.2 **Infrastructure**  
Facilities, equipment and services needed for the operation of an organisation.
- 3.3 **Management system**  
Set of interrelated or interacting elements of an organization to establish policies, objectives and processes to achieve those objectives.
- 3.4 **Policy**  
Intentions and direction of an organization as formally expressed by its top management.

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| 4 | Policy Statement | 2 |
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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.

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| <b>5</b> | Responsibilities | 3 |
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## 5.1 **Board**

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

## 5.2 **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.

## 5.3 **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.

## 5.4 **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.

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| <b>6</b> | Communication | 3 |
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This policy is communicated through the company shared drive/intranet, company website ([www.polycohealthline.com](http://www.polycohealthline.com)) and company notice boards, and forms part of the induction training programme and will be made available to all interested parties.

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

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| <b>6</b> | Document Control | Revision Record |
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## Revision Record

| Document Owner/Department |                                                                                                                   | Technical                          |                 |                | Document/change Approval |                          |                       |
|---------------------------|-------------------------------------------------------------------------------------------------------------------|------------------------------------|-----------------|----------------|--------------------------|--------------------------|-----------------------|
| Revision Number           | Description of Change                                                                                             | NCR Ref                            | Review by       | Date of change | Name                     | Position                 | Signature             |
| 1                         | Imported from HPC system                                                                                          | N/A                                | Ellie Farrow    | November 2017  | Dave Greenwood           | Director                 | <i>Dave Greenwood</i> |
| 2                         | Added reference to BRC CP issue 4. and PAS 29                                                                     | N/A                                | Ellie Farrow    | 16/01/2019     | Dave Greenwood           | Director                 | <i>Dave Greenwood</i> |
| 3                         | Addition of PPE statement from BSIF                                                                               | N/A                                | David Langridge | 5/12/2019      | Dave Greenwood           | Director                 | <i>Dave Greenwood</i> |
| 4                         | Addition of BRC Packaging issue 6, and MDR, added in communication                                                | N/A                                | Karen Gunning   | 18/2/2020      | Andy Blewett             | General Manager          | <i>Andy Blewett</i>   |
| 5                         | Updated to annually review, included UK MDR, added in revision record                                             | N/A                                | Karen Gunning   | 09/8/2021      | Andy Blewett             | General Manager          | <i>Andy Blewett</i>   |
| 6                         | Change policy format to include scope, purpose, responsibility and communication. Remove BRC PM6.                 | N/A                                | Karen Gunning   | 10/01/2023     | Andy Blewett             | Executive Director       | <i>Andy Blewett</i>   |
| 7                         | Annual Review Inclusion of a review date and update approval to Chief Commercial Officer                          | CAPA-I-2024-030<br>CAPA-I-2024-032 | Karen Gunning   | 16/07/2024     | Brett Wakeley            | Chief Commercial Officer | <i>Brett Wakeley</i>  |
| 8                         | Update the range of products to include tourniquets and medical face masks. Include the ISO 9001 addendum A1:2024 | 2025 QMS Management Review Action  | Karen Gunning   | 24/03/2025     | Brett Wakeley            | Chief Commercial Officer | <i>Brett Wakeley</i>  |
| 9                         | Document Under Annual Review                                                                                      | 2026 QMS Management Review Action  | Karen Gunning   | 26/04/2026     | Brett Wakeley            | Chief Commercial Officer | <i>Brett Wakeley</i>  |

## Training Record

|                                                                                                       |                                                                                                          |  |      |   |
|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|--|------|---|
| <b>Training Required</b> -Tick relevant box                                                           | Yes                                                                                                      |  | No   | ✓ |
| <b>Training Level</b> -Tick relevant box                                                              | Full                                                                                                     |  | Read |   |
| <b>Personnel</b> -List departments and / or job functions of those that need to train in the document | Training in revision 09 not required because the purpose and significance of the policy has not changed. |  |      |   |

## Associated Documents

|                                                   |                |                                                |   |    |  |
|---------------------------------------------------|----------------|------------------------------------------------|---|----|--|
| <b>Associated document reference</b> – list below |                | Does the associated document require revision? |   |    |  |
| PH-TLD-001                                        | Quality Manual | Yes                                            | ✓ | No |  |