

Viamed Ltd

Risk Management Statement

1. Introduction

Viamed Ltd recognises that effective risk management is fundamental to delivering high-quality products and services and maintaining compliance with applicable standards and regulations. Our approach ensures that risks are proactively identified, assessed, controlled, and monitored across all areas of the business.

2. Policy Objectives

- Integrate risk management into decision-making and daily operations.
 - Minimise exposure to operational, financial, reputational, health & safety, environmental, and regulatory risks.
 - Comply with ISO 13485:2016 and other applicable UK and international medical device regulations as they apply to the distribution and manufacture of medical device accessories.
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3. Governance & Responsibilities

- **Managing Director:** Has ultimate responsibility for risk management policy, implementation, and oversight.
- **ISO Controller:** Manages risk related to quality assurance, supplier review, non-conformance, feedback, and system objectives.
- **Health & Safety Controller:** Ensures health and safety risks are assessed and mitigated.
- **IT Controller:** Oversees cyber security, system validation, backup, and infrastructure risks.
- **Accounts Controller:** Manages financial, VAT, and sales processing risks.
- **Other Departmental Controllers:** Are responsible for identifying and reporting risks within their functional areas.

All roles are defined in accordance with our internal Quality Management System (QMS) and documented in our VOP 21 procedure.

4. Approach to Risk Management

- Risks are assessed and recorded across all departments using consistent criteria.
- Each risk is evaluated for likelihood and impact.

- Appropriate controls are implemented to mitigate risks.
 - All identified risks are reviewed regularly as part of the Management Review process.
 - Risk assessments are aligned with Viamed's post-market surveillance, complaints, and feedback systems.
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5. Continuous Improvement

We maintain a culture of continuous improvement and ensure our risk management processes are reviewed and updated as required. Feedback, audits, non-conformance reviews, and employee input are used to refine our approach.

For more information or to report a concern related to risk management, please contact:
compliance@viamed.co.uk