

Viamed Ltd

Complaints & Vigilance System Statement

1. Introduction

Viamed Ltd operates a structured and transparent system for the management of customer complaints, product feedback, and post-market surveillance. This ensures the continuous monitoring of safety and performance across our distributed medical devices and test equipment, and helps maintain compliance with UK regulations and ISO 13485:2016.

2. Objectives

- Ensure all complaints and feedback are handled in a timely, consistent, and traceable manner.
- Fulfil regulatory requirements for post-market surveillance and vigilance.
- Detect trends, risks, or non-conformities requiring corrective or preventive action.
- Maintain a clear audit trail for all issues raised, actions taken, and resolutions.

3. Definitions & Scope

- **Feedback** includes positive and negative input received from customers, users, or suppliers relating to products, services, or staff interactions.
- **Complaints** include any report of dissatisfaction related to product performance, safety, effectiveness, or service.
- **Vigilance Issues** refer to safety-related incidents or potential risks that may require notification to regulatory authorities.

The system applies to all Viamed-supplied products and services, including those for which we act as a UK Responsible Person (UK RP).

4. Procedure Summary

- All complaints and feedback are logged in our internal system (Intrastats) under appropriate categories.
- Returned products are processed via SRS with documented tracking.
- Each complaint is evaluated for vigilance implications.
- Root cause analysis and corrective actions are initiated where required.

- Results and patterns are reviewed in Management Review meetings.
- Where applicable, we report incidents to manufacturers and cooperate with the MHRA.

5. Commitment to Improvement

Our complaints and vigilance system is a key part of our Quality Management System. It supports our commitment to safety, compliance, and continuous improvement.

For further information or to report a complaint or concern, please contact:

compliance@viamed.co.uk