

VOP			
Operating sub Process			
<u>Viamed Ltd</u>			
<u>VOP 05 Supplier Management, Purchasing and Supplier Performance</u>			
Created:	27/03/06	VOP 05	
		See the Route Map for related ISO Standards.	Page 1 of 6

SCOPE

This procedure establishes the system used by Viamed Ltd for the selection, approval, purchasing, monitoring and ongoing review of suppliers and subcontractors.

It defines how suppliers are approved, how products and services are purchased, how supplier performance is monitored, how supplier returns and non-conforming goods are managed, and how Viamed ensures that suppliers continue to meet quality, regulatory, ethical and sustainability requirements.

This procedure applies to all suppliers providing products, components, consumables, packaging materials, calibration services, repair services, subcontract manufacturing, logistics services and any externally provided products or services that may affect product quality, regulatory compliance or business operations.

This procedure supports compliance with ISO 13485, applicable regulatory requirements, the Modern Slavery Act 2015 and Viamed's commitments to responsible sourcing, sustainability and continual improvement.

RESPONSIBILITIES

The Managing Director has overall responsibility for supplier approval, purchasing controls, supplier performance and ensuring that this procedure is implemented and maintained.

The Warehouse Controller is responsible for the day-to-day management of purchasing activities, maintaining supplier records, monitoring supplier performance and coordinating supplier reviews.

Department Managers and Supervisors are responsible for identifying purchasing requirements, defining supplier requirements and reporting supplier performance issues where identified.

Employees involved in purchasing, receiving goods, supplier reviews or supplier management are responsible for ensuring purchases comply with this procedure and for reporting any quality, regulatory or supplier-related concerns.

Supplier performance is reviewed as part of the company's Management Review process.

OBJECTIVES

The objectives of this procedure are to ensure that:

- Suppliers consistently provide products and services that meet Viamed's quality and regulatory requirements.

- Purchased products conform to specified requirements before acceptance.
- Supplier performance is monitored and continually improved.
- Purchasing decisions consider quality, regulatory compliance, service, sustainability and ethical standards.
- Risks associated with suppliers are identified and appropriately managed.
- Supplier relationships support continual improvement and responsible sourcing.
- Regulatory and customer requirements are maintained throughout the purchasing process.

SUPPLIER MANAGEMENT

All suppliers providing products or services affecting product quality or business operations shall be assessed before approval and monitored throughout the duration of their relationship with Viamed Ltd.

Suppliers are maintained within the Intrastats Approved Supplier List, which records supplier information, review status, supplier category, quality approvals and other relevant compliance information.

Suppliers are categorised within Intrastats according to the nature and criticality of the products or services supplied. Categories may include Critical Suppliers, Secondary Suppliers, Packaging Suppliers, Utility Providers, Professional Services, Promotional Suppliers, Facilities & Maintenance, IT & Communications and other classifications considered appropriate by management.

The level of supplier assessment and monitoring shall be proportionate to the risk associated with the products or services supplied.

PURCHASING

Purchase Orders are generated through the Intrastats management system following receipt of an authorised purchasing requirement.

Purchase Orders shall clearly specify all information necessary to ensure that suppliers understand the company's requirements, including where appropriate:

- Product description
- Manufacturer or supplier part number
- Quantity
- Agreed pricing
- Delivery requirements
- Packaging requirements
- Inspection or testing requirements
- Traceability requirements
- Serial, batch or lot number requirements
- Certificates of Conformity or other documentation
- Special customer or regulatory requirements

Purchase Orders shall be authorised in accordance with company purchasing controls before being issued to suppliers.

Electronic purchasing records are retained within Intrastats to maintain full traceability.

SUPPLIER APPROVAL

New suppliers shall be assessed before being added to the Approved Supplier List.

Supplier approval shall be based upon risk and may include consideration of:

- Quality Management certification (ISO 13485, ISO 9001 or equivalent)
- Technical capability
- Product quality
- Regulatory compliance
- Delivery performance
- Historical performance
- Financial stability where appropriate
- Business Continuity arrangements
- Cyber Security arrangements where applicable
- Environmental performance
- Carbon Reduction commitments
- Modern Slavery compliance
- Ethical business practices
- Ability to meet customer-specific requirements

Where suppliers do not hold recognised certification, additional assessment may be undertaken through supplier questionnaires, historical performance or other suitable evaluation methods.

SUPPLIER REVIEW AND MONITORING

Approved suppliers shall be reviewed at planned intervals appropriate to their level of risk.

Supplier Reviews may consider:

- Product quality
- Delivery performance
- Returns
- Supplier responsiveness
- Customer complaints
- Non-conforming products
- Corrective actions
- Historical performance
- Certificates and approvals
- Pricing and commercial performance
- Supply chain resilience
- Ongoing regulatory compliance

The frequency and scope of supplier reviews shall be proportionate to the level of risk presented by the supplier.

Supplier Review records are maintained within Intrastats and form part of the Management Review process.

Supplier reviews may result in improvement actions, changes to supplier risk classification, additional monitoring requirements or removal from the Approved Supplier List where appropriate.

SUPPLIER RISK ASSESSMENT

Supplier risks are assessed to support business continuity, regulatory compliance and responsible sourcing.

Risk assessment may include consideration of:

- Country of operation
- Country of manufacture
- Sole-source suppliers
- Supply chain resilience
- Political or geographical risk
- Product criticality
- Availability of alternative suppliers
- Business Continuity arrangements

Risk assessments are reviewed periodically or whenever significant supplier changes occur.

ETHICAL, SOCIAL AND ENVIRONMENTAL RESPONSIBILITY

Viamed Ltd is committed to responsible procurement and ethical sourcing throughout its supply chain.

Supplier reviews may include assessment of:

- Modern Slavery compliance
- Human Rights practices
- Ethical labour standards
- Acceptance of Viamed Ltd's Supplier Code of Conduct.
- Anti-Bribery and Corruption controls
- Environmental policies
- Carbon Reduction Plans
- Sustainability initiatives
- Responsible sourcing
- Fair Payment practices
- Significant ethical, labour or environmental incidents
- Corrective actions implemented by suppliers

Where appropriate, suppliers may be requested to provide documentary evidence supporting these requirements.

PRODUCT AND REGULATORY COMPLIANCE

Where appropriate to the products or services supplied, suppliers shall provide documentation demonstrating compliance with relevant regulatory and customer requirements.

This may include:

- Certificates of Conformity
- Product certifications
- REACH declarations
- RoHS declarations
- Material specifications
- Packaging compliance documentation, including Packaging and Packaging Waste Regulation (PPWR) declarations and supporting technical documentation where applicable.
- Traceability information
- Technical documentation
- Batch or serial number information
- Other documentation required by legislation or customers

Supplier documentation shall be maintained where appropriate to support regulatory compliance and customer requirements.

SUPPLIER PERFORMANCE

Supplier performance is continually monitored through information recorded within Intrastats and other company records.

Performance indicators may include:

- On-time delivery performance
- Delivery accuracy
- Product quality
- Customer complaints
- Product returns
- Supplier returns
- Non-conformances
- Credits received
- Corrective actions
- Responsiveness
- Supplier Review outcomes

Where supplier performance falls below acceptable standards, corrective action may include increased monitoring, formal review, suspension or removal from the Approved Supplier List.

NON-CONFORMING GOODS AND SUPPLIER RETURNS

Products failing incoming inspection or otherwise found to be non-conforming shall be quarantined and managed in accordance with the relevant Incoming Inspection and Non-Conforming Product procedures.

Where goods require return to the supplier, appropriate Return Material Authorisation (RMA) processes shall be followed.

Supplier Returns are managed through Intrastats to maintain complete traceability of returned products, associated communications and corrective actions.

Supplier performance relating to returned products forms part of future supplier reviews.

PRODUCTS OUTSIDE THE SCOPE OF REGISTRATION

Where products or services are obtained from suppliers outside the company's normal approval process, the associated risks shall be assessed before supply wherever practical.

Where products originate from suppliers not holding recognised quality certification, this shall be identified where appropriate, and additional verification or inspection may be undertaken before products are accepted or supplied.

Any exceptions to the normal supplier approval process shall be authorised by the Managing Director and appropriately documented.

RECORDS

The following records are maintained where applicable:

- Approved Supplier List
- Supplier Review Records
- Supplier Risk Assessments
- Purchase Orders
- Supplier Returns
- Supplier Performance Records
- Regulatory Compliance Documentation
- Supplier Certifications
- Supplier Questionnaires
- Packaging Compliance Documentation