VOP 28
Operating sub Process
Distribution of Supplier Products to the UK/EU

		VOP 28	
		See the Route Map for related ISO Standards.	**Page 1 of 3**

SCOPE

This procedure defines the processes and documentation requirements for distributing supplier products into the UK and EU.
It applies to all suppliers of medical devices and related products provided for onward distribution. It is used in conjunction with the individual sub procedures, which show the relevant information necessary.

RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to. To oversee all requirements of this procedure, with delegated nominees adding to the audit team if and where necessary.

OBJECTIVES

It is the Objective of this VOP to document the requirements for distributing supplier products into the UK and EU. It relates to the suppliers of medical devices and related products provided to Viamed for onward distribution.

SUPPLIER CATEGORISES

Suppliers are categorised into four groups:
1. Category 1: Does not Supply Devices for resale.
2. Category 2: Supplys Devices without a formal agreement.
3. Category 3: Supplys Devices with a formal agreement.
4. Category 4: Supplys Devices with a formal agreement where labels state “Distributed by …..”.

Category 2: Suppliers without a Formal Agreement

Minimum Documentation Requirements
- EC Declaration of Conformity (per product or family)
- CE/UKCA certification (if applicable)
- Current ISO 13485 certificate (if available)
- Instructions for Use (IFU)
- Product labels and packaging samples
- Records of incoming checks (condition, correct labelling, damage)

Our Actions
- Verify all incoming shipments for labels, IFUs, and packaging condition
- Record distribution checks in receiving log
- Maintain evidence of supplier certificates and DoC on file
- Escalate and log any product issues, complaints, or incidents

- Conduct periodic review of supplier compliance (minimum every 2 years)

Category 3: Suppliers with a Formal Agreement

Minimum Documentation Requirements
- Signed Supplier Agreement covering quality and regulatory obligations
- EC Declaration of Conformity (per product or family)
- CE/UKCA certification (if applicable)
- Current ISO 13485 certificate
- Instructions for Use (IFU) and product labels
- Change notifications and correspondence regarding product updates
- Complaints and vigilance records shared with supplier

Our Actions
- Verify all incoming shipments for labels, IFUs, and packaging condition
- Maintain signed supplier agreement and renew as required
- Conduct annual review of supplier certificates (ISO 13485, DoC, CE/UKCA)
- Ensure complaints and incident records are fed back to supplier per agreement
- Maintain traceability records (lot/serial numbers) for all distributed products
- Document supplier reviews in annual management review

Category 4: Suppliers with Formal Agreement and “Distributed by Viamed” on the Label

Minimum Documentation Requirements
- Signed Supplier Agreement including allocation of regulatory responsibilities
- EC Declaration of Conformity (per product or family)
- CE/UKCA certification (if applicable, with Notified Body details)
- Current ISO 13485 certificate (scope must cover product manufacture)
- Instructions for Use (IFU), labels, and packaging artwork (with “Distributed by Viamed”)
- Master copies of approved artwork under document control
- Change notifications (labelling, IFU, design, site changes)
- Complaints and vigilance records
- Evidence of Post-Market Surveillance (PMS) activities
- Distribution control records (label checks, incoming verification logs)

Our Actions
- Verify all incoming shipments, ensuring “Distributed by …..” labelling and IFUs are correct
- Maintain master versions of labels and IFUs under document control
- Conduct annual review of ISO 13485, DoC, and CE/UKCA certification validity
- Maintain robust traceability: lot/serial number records for product lifetime + 10 years
- Collect and analyse PMS data, including customer feedback and incident reporting
- Notify supplier of complaints, incidents, or recalls within agreed timelines
- Maintain readiness for audits, demonstrating supplier documentation and records
- Escalate regulatory issues immediately to Quality Management and Regulatory teams

Records and Retention
- All supplier-related documentation (certificates, DoCs, agreements, IFUs, labels, correspondence) shall be retained for at least the lifetime of the product plus 10 years, in line with MDR requirements.
- Distribution records (lot/serial traceability, incoming checks) shall be retained for the same period.

References
- ISO 13485:2016, clauses 7.4 (Purchasing), 7.5 (Production & Service Provision), 8.2 (Monitoring & Measurement)
- EU MDR (2017/745) and UK MDR 2002 (as amended)
- VOP-XX Supplier Evaluation and Approval
- VOP-XX Post-Market Surveillance