VOP			
Operating sub Process			
Supplier Control,Supplier Review, Purchase Orders, Supplier Returns and Rejection			
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		Viamed Ltd ISO13485:2016: 4.1.5, 7.4.1, 7.4.2 VST Ltd ISO9001:2015: 8.4.1, 9.1.3, 8.4.2, 8.4.3	Page 1 of 4
QC06			

SCOPE

This procedure is established to describe the system used within the company for the control of purchasing of product and evaluation / assessment of suppliers and sub-contractors. 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. It is the responsibility of the relative supervisors to ensure that their requirements are made clear. The Warehouse Controller is responsible for the ongoing evaluation of suppliers / sub-contractors.

PURCHASING

A warehouse request is submitted by a member of staff. This is picked up by the Warehouse controller, they then generated a Purchase order POR in our accounts package. To cover the supply of products for warehouse stock, or immediate customer delivery.

The purchase order is raised for goods or materials as required, and the details entered into the correct supplier on the accounts package. The purchasing documents should clearly describe requirements, i.e. quantity, price, description. The printed purchase order form is then forwarded to a Director for approval. Once it has been approved it can then be sent to the supplier by the office. Purchase order must contain a supplier code – i.e. the field should not be blank. In the case of an unknown supplier code, the line must be counter signed by a director.

Requisitions for Orders may be initiated by:
Engineers – stock needed for production or repairs.
Office staff – when they check stock for customers order and it show we will not have sufficient stock.
Warehouse controller – to bring stock items up to minimum level or against goods not already in stock or already ordered, to supply customer orders in hand.
All POR are countersigned by a Director or produced by a director.

Purchase orders are processed by the following means;

- Addressee abroad – By Fax/Email
- Non urgent orders By – Post/Email
- Urgent orders – By Fax/Email
- Extremely urgent orders – By Telephone/Email, (the POR still needs to be printed and signed off)

Purchase Order Number is generated automatically. Purchase Orders contain all relevant data to the supplier, part numbers or product codes, description and quantity.

The printed copy is made for company records and supplier confirmation. Then filed correctly, in the goods in department, in the POR file, in purchase order number order. So that when the goods come in, they can be checked against our original paperwork. When the goods are received this is stamped as such. Then the accounts package and Intrastats are checked and barcodes produced booking into stock.

The Purchase Order must specify any requirements for inspection and tests, and any certification required, include special instructions for packaging, labelling or delivery. Additional information where appropriate is advised e.g.

- Quoted price when applicable.
- "Urgent Please" if supply is required urgently.
- "Partial shipment acceptable/not acceptable".
- Preferred method of shipment.
- If supplier needs to know for traceability of specified instruments or service. We can give the customer or instrument details.
- Requirement on POR for serial numbers/ LOT numbers / batch numbers for traceability.
- Conformity Certification needs to be requested from the supplier when required.

Purchase Orders will be reviewed and authorised by the Managing Director, Director or Warehouse Controller.

It is the responsibility of the individual raising the purchase order to ensure that all the relevant and correct information is entered onto the purchase order. It is the responsibility of the person receiving the Intrastats task to ensure the copy purchase orders are filed accordingly.

ASSESSMENT OF SUPPLIERS / SUB-CONTRACTORS

All products provided to us under cover of its ISO 9001/13485 must be procured from a Quality Assured Source, or is internally QA / Verified. When a customer orders products, in accordance with the companies Approved Supplier List, then a quality assured source will be:-

- Companies listed in the DTI Quality Assurance Register of assessed companies current issue, and who supply within their declared scope.
- Companies assessed by certification bodies outside the UK to equivalent systems.
- A Company specifically nominated by a customer in his order will also be considered a Quality Assured Source for that particular customer, or where the customer has specified the product by brand or specific part number.

APPROVAL OF SUPPLIERS

New products will be considered by the Managing Director, by assessment of suppliers capability to meet the required quality standard. At an acceptable delivery date, to verify the firm maintains batch segregation, inspection and test records. A Supplier/Sub contractor questionnaire (Form QC06) will be used to approve suppliers.

An Approved Supplier List of approved Suppliers/Sub contractors will be maintained by Managing Director or his chosen representative in Intrastats, which will distinguish between Quality Assured and non-Quality Assured Sources.

In certain instances, commercial considerations may result in the use of a supplier not included on the approved supplier list. In these instances the level of goods inwards inspection is to a higher standard until such time as the supplier has passed assessment and been entered onto the Approved Supplier List.

At least once per year all suppliers will be re validated or re-assessed.

An Approved Supplier List of current suppliers is available and maintained in Intrastats. This list is monitored and evaluated on a regular basis, and formally reviewed annually for the management review. The determination of supplier suitability is made on the basis of Third party approval, historical acceptable performances, pricing, delivery or other such factors as may be deemed appropriate.
In certain instances, commercial considerations may result in the use of a supplier not included on the approved supplier list. In these instances the level of goods inwards inspection is to a higher standard until such time as the supplier has passed assessment and been entered onto the approved Approved Supplier List.

Information received from all departments, on an annual basis, will be taken into consideration for review of this Approved Supplier List.

SUPPLIER QUALITY CONTROL

The Managing Director will be responsible for ascertaining whether Suppliers / Subcontractors performance is satisfactory or unsatisfactory. They can use details based on the following feedback from Issues:
Rejects as a result of non-conformance to purchase order.
Rejects as a result of damage in transit.
Incorrect or lack of correct documentation.
Incorrect quantities delivered.
Customer complaints.
Length of time taken in correcting situation
Corrective action will be taken by the Managing Director

REJECTED GOODS

Where goods fail incoming Inspection as per VOP 06. They will then be quarantined and put on hold awaiting return to the supplier or agreed action.
If a product is rejected due to, damage in transit, failure to meet relevant specification, failure to meet IEC601 safety specification, it is placed in the Return To Supplier ducket, specific to each supplier.
The supplier will be contacted and an RMA requested. The supplier will be asked for confirmation and once we receive conformation the goods scanned to the returns ducket / shelf. The goods to be returned to the supplier will be done through Intrastats Supplier Returns.

CERTIFICATION

Conformity/Test Certificates need to be obtained from the supplier when they are offered by us, to the customer. Information is copied from manufacturer/supplier

certification. The original certificate is sent to the customer and a copy retained with the customers ORD paperwork.

PRODUCTS OUTSIDE THE REGISTRATION

Any product which is not included in the Registration will be clearly identified in the covering documentation so that there can be no misunderstanding on the part of the customer.

Similarly if a supplier has not been approved as specified Approval of Suppliers, their products must not be sold without them being clearly identified and confirmed in the covering documentation, as follows - "This item procured from a non ISO 9001 source".