VOP			
Operating sub Process			
Feedback Customer Complaints Vigilance and Notifications Viamed Ltd			
Created:	24/10/2017	VOP 19	
		See the Route Map for related ISO Standards.	Page 1 of 5

SCOPE

This procedure is established to describe the system used within the company for the control of Complaints, Vigilance and Notifications within Viamed Ltd. 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, and that the relevant documentation is fully completed.

During Post market Surveillance Reviews; Complaints, Feedback, Non Conformances, QA Failures and Repairs will be evaluated on a continuous basis to ensure no pattern of failure is emerging.

OBJECTIVES

It is the Objective of this VOP to demonstrate compliance of the Surveillance of Complaints, Feedback, Non Conformances, QA Failures and Repairs, for Post market Surveillance and Notified Bodies.

FEEDBACK – DEFINITIONS

This is when a customer, supplier or other persons, contact the company to give an opinion on how we, as a company, as a whole, our products, services or staff have behaved. If we have met expectation or not met expectations.
It can be positive or negative and it is an opportunity for us as a company to learn and improve, using the input from others. All feedback will be logged in Intrastats issues. All feedback is reviewed in the Management Review Meeting.

Feedback can relate to routine calibration, product maintenance, technical inquiries, customer suggestions for more product features, new products asked for, pricing issues, credit inquiries, delivery periods, problems with delivery companies, stock shortages, staff interactions etc.

FEEDBACK RECEIVED

When a feedback is received by any means, Telephone, Email, Fax, Post or in Person. We log the details in to the Contact Management system in Intrastats, under the correct company then contact. If they are not already in, we add them and include as many details as possible. If they are already in, we check the details that are already in are correct and up to date. These will be recorded in Intrastats, under the headings Product Feedback Positive, Product Feedback Negative, Feedback Positive and Feedback Negative. This issue should be sent to a Director or the Managing Director.

COMPLAINTS – DEFINITIONS

A Complaint is defined as any report, written or oral, with or without a return product, expressing customer dissatisfaction with:
Device identity: Labelling errors

Reliability: Inability to perform in a consistent manner throughout the warranty period or specified service period.
Safety: Possible harm to patient or operator.
Effectiveness: Inability to perform as intended.
Performance: Inability to perform in compliance with the published specifications.
Durability: Inability to perform throughout warranty period or specified service period.
Service from the company: Unsatisfactory service or response from the company.
Service from the staff: Unsatisfactory service or response from a member of staff, or inappropriate behaviour.
System faults or failures: Wrong paperwork, wrong goods, wrong addresses etc.

COMPLAINTS EXCEPTIONS

Routine calibration, product maintenance, technical inquiries, product updating to current approved revision levels, customer suggestions for more product features, credit inquiries, pricing issues, delivery periods and stock shortages etc, are not considered complaints.

COMPLAINTS RECEIVED

When a complaint is received by any means, Telephone, Email, Fax, Post or in Person, we log the details in to the contact management system in Intrastats, under the correct company then contact. If they are not already in we add them and include as many details as possible. If they are already in, we check the details that are already in are correct and up to date. This will be recorded in Intrastats under the headings Customer Complaints. This issue should be sent to a Director or the Managing Director.

If a complaint is received by phone and the complaint cannot be answered satisfactorily by the office staff, then the call should be passed to the Technical / Sales staff or the Managing Director or a Director.
If any complaint comes in and is not a user associated problem, we request the item or accessory be returned back to us, generate a returns number from Intrastats and quote the number to the customer.
We fully record details of complaint and the item being returned in the SRS system.

All Complaints Issues must contain reasoning to explain why the complaint is or is not a vigilance issue and if there are any risks involved.

GOODS RETURNED

Upon receipt to Goods In, we place the product in a ducket and print a service repair form from Intrastats, SRS. Which is raised by the Goods In staff which should include supply date referenced on it. Then it is entered in the Deliveries section on Intrastats (Ref procedure VOP 20).
This is then passed to the Engineer for examination with a copy of any necessary paperwork, the complaint report, SRN barcodes and the SRS paperwork. If repaired the procedure will be as in VOP 09.

Copy of complaint will be sent to the Managing Director, who will investigate those problems associated with damaged goods or failure to meet specification in spite of QA Inspection. A report will be produced including:
Create a follow up / related Issue – With a time for Completion
Immediate Action Plan
Corrective Action Plan
Corrective Action
Risk Analysis
Confirmation of Resolution

If the complaint is a failure to comply with a specification, a repeated failure, or a premature failure (e.g. sensors), then the substance of the complaint and preferably the written complaint should be copied to the original manufacturer (See procedure VM/COP/06).

If the complaint is common or has a known explanation, the complainant should be informed explaining the current position and the action being taken by ourselves and / or the original supplier.
If the problem has no present solution the complaint should remain live on Intrastats and be filed in the CURRENT COMPLAINTS file, with the SRS, and all other relevant paperwork until an answer is found. The customer is contacted and informed of the position. The Managing Director reviews progress with the person responsible for investigating the problem and these are reviewed as part of the management meetings.
An issue under the appropriate company Customer Complaints header should also be generated and sent to supervisor or management.
The Complaint Report is filed in the complaints file and attached to the contact in Intrastats.

REFERENCE DOCUMENTS
Customer Complaint Report (QC12)
Customer Complaint Report Index (QC11)
Risk assessment for Manufacturer Incident Report MIR 7.2.1. Notification (QC44)
Non Conformance Form (QC 21)

VIGILANCE SYSTEM
Should the complaint escalate to withdrawal of suspected product or require advisory notices, QC11 paper file index will be added to, and refer back to the Intrastats Issue number. The QC44 Risk assessment form started.

All correspondence regarding the complaint shall be logged against the original customer complaint issue number, all emails / forms can be scanned and linked to the Issue number

Vigilance system will be carried out in accordance with the current MEDDEV 2.12-1. Task Id 128 to ensure this is current.

The version of MEDDEV 2.12-1 is check for version control once per calendar year.

WITHDRAWAL OF SUSPECT PRODUCT OR NOTICE FROM SUPPLIER

Substantiated complaints which could be dangerous or harmful, will require notification to the relevant Competent Authority. In this situation a complete list of users or locations should be assembled see VM3/COP/10.02.

If appropriate the Managing Director will arrange to withdraw remaining items from stock.

Sub Distributors must also keep records of destinations of products distributed and have in existence, recall methods.

RECALL OF SUSPECT PRODUCT

See VM3/COP/10.02 For the product recall process.

REPAIR OF SUSPECT PRODUCT

Repairs will be in accordance with VOP 09
Customer complaint Report QC12 will be raised for the duration of the recall.

FORMAT OF ADVISORY NOTICE

Users will be contacted by letter, Email, Fax, or Telephone followed by a letter notifying them of the problem. The information in the letter should contain a clear description of the problem and its possible effects. A solution if available. Advice on how to circumnavigate the problem, if a method exists. Copies of the original manufacturers information should be enclosed. Information on Order No, Invoice Number, Date of purchase, Equipment type and Equipment Serial number should be included where available.

A list of users / purchasers can be obtained as in VM3/COP/10.02.

EBME and / or engineering departments should be informed.

Incidents as defined in the MDR will be reported as per MEDDEV 2.12-1, Manufacturer Incident Report MIR 7.2.1. Details of which can be found in the EC Manufacturer Incident Report (MIR) updates pages and guidance documents.
https://docs.oracle.com/en/industries/health-sciences/argus-safety/8.2.3/aeoas/support-manufacturer-incident-report-mir.html

Response will be immediate and instant referral to the MDR guidelines following the Incident Action plan as per MEDDEV 2.12.-1. Risk assessment to determine MDR notification is carried out on (QC44)
The Notified Body and any other National body requiring notification will be informed at the same time
.
Notification of incidents will be indicated on Customer Complaint Report Index (QC11) & (QC12).

NOTIFICATION OF NOTIFIED BODIES.

Where it is identified that product has been shipped abroad while following VM3/COP/10.02.
Any external notified bodies / medical authorities will be informed of the recall / advisory notice, e.g.
Sales to UK - M.H.R.A
Sales to Canada – Canada Health will be informed following CMDCAS Guidance Documents
Sales to Taiwan – Food and Drug administration, ministry of health and welfare, TFDA.

BSI Technical Manager shall be Emailed, and BSI's current reporting process carried out.

TIME SCALE OF REPORTING

The following time lines apply in a case of:
Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness.

Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after the link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

Others: IMMEDIATELY (without any delay that could not be justified) after the link between the device and the event but not later than 15 elapsed calendar days following the date of awareness of the event. If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the report must be submitted within the time frame required for that type of INCIDENT.