I. **DEFINITION**

A Complaint is defined as any report, written or oral, with or without a return product, expressing Customer dissatisfaction with:

II. Device identity: labelling errors

III. Reliability: Inability to perform in a consistent manner throughout the warranty period or specified service period.

IV. Safety: Possible harm to patient or operator.

V. Effectiveness: Inability to perform as intended.

VI. Performance: Inability to perform in compliance with the published specifications.

VII. Durability: Inability to perform throughout warranty period or specified service period.

VIII. **Definition Exceptions:**

Routine calibration, product maintenance, technical inquiries, product updating to current approved revision levels, customer suggestions for more product features, credit inquiries, etc., are not considered complaints

IX. REFERENCE DOCUMENTS

X. Customer Complaint Report (QC12)

XI. Customer Complaint Report Index (QC11)

XII. Service Repair Note (QC09).

XIII. Risk assessment for MDD Notification (QC44)

XIV. TELEPHONE COMPLAINTS

XV. Note name and address in diary (daily telephone log). Record details of complaint in diary and raise a customer complaint report (QC12).

XVI. If the complaint cannot be answered pass the complaint to the Managing Director or Financial Controller or Technical Staff for investigation.

XVII. If the complaint cannot be answered i.e. Not a user associated problem request the instrument or accessory be returned and record the complaint on the customer complaints Report Index (Form QC11).

XVIII. Obtain Serial Number and check for warranty from stock book.

XIX. If required send a replacement with full Delivery Note etc. and request faulty goods be returned in same packing.

XX. If appropriate arrange for a Sales Person or engineer to visit the site.

XXI. In this case the Sales Person or Engineer will raise the Service Repair Note (QC09).

XXII. GOODS RETURNED TO VIAMED

XXIII. Upon receipt, the product will be boxed and a service repair form, Form QC 09 (SRN) raised by the office staff with supply date referenced on it. If a repair it is logged to the Repairs Book. (Ref procedure VM/COP/09 Section 4.1.2).

XXIV. Pass to Engineers for examination with a copy of any accompanying paperwork, the complaint report and the SRN. If repaired the procedure will be as in VM/COP/09.

XXV. Copy of complaint to 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 Corrective Action will be recorded.

XXVI. 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).

XXVII. If the complaint is common or has a known explanation a letter should be sent explaining the current position and the action being taken by ourselves and/or the original supplier.

XXVIII. If the problem has no present solution the complaint should be filed in the CURRENT COMPLAINTS file with the SRN, and all the relevant copies of the paperwork until an answer is found. The customer is contacted and informed of the position, and the Office Manager reviews progress with the person responsible for investigating the problem.

XXIX. The Complaint Report is filed in the complaints file and the Hospital/customer file

XXX. <u>WITHDRAWAL OF SUSPECT PRODUCT</u>

XXXI. 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. This is taken from the Invoice File/Stock book/or white copies. Records are available back to 1977.

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

XXXIII. Where a supplier contacts Viamed concerning suspect goods already delivered procedure 5.1 and 5.2 will be followed as appropriate.

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

XXXV. Distributors will be requested to complete Declaration of 5.4

XXXVI. <u>RECALL OF SUSPECT PRODUCT</u>

XXXVII. Destination of product can be located in INVYRCOM (or similar) File which comprises all items sold since 1977.

XXXVIII. White copies will manually locate product destinations

XXXIX. All Invoices (Pink copies) are held for eleven years in Archives.

XL. <u>REPAIR OF SUSPECT PRODUCT</u>

XLI. Repairs will be in accordance with VM/COP/09

XLII. Customer complaint Report QC12 will be raised for the duration of the recall

XLIII. <u>FORMAT OF ADVISORY NOTICE</u>

XLIV. Users will be contacted by letter , 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

XLV. A list of users/purchasers can be obtained as in (5) & (6)

XLVI. EBME and/or engineering departments should be informed.

XLVII. Incidents as defined in the MDD will be reported on form Appendix 3 (MDD) and CMDCAS guidance documents

XLVIII. Response will be immediate and instant referral to the MDD guidelines following the Incident Action plan on Appendix 4 .Risk assessment to determine MDD notification is carried out on (QC44)

XLIX. The Notified Body and any other National body requiring notification will be informed at the same time as the MDD

Notification of incidents will be indicated on Customer Complaint Report Index (QC11) & (QC12)