CORRECTIVE AND PREVENTIVE ACTION

1.0 GENERAL

1.1 It is the policy of the Company to establish and maintain documented procedures to record all reports of non-conformities or defective products, from whatsoever source the report may arise, to investigate all such reports and take corrective and preventive action to prevent the recurrence of the non-conformance.

1.2 It is also the policy of the Company to develop a procedure for the documentation of complaints received from customers, relating directly to any product or service provided by the company.

2.0 RESPONSIBILITY

2.1 It shall be the responsibility of the Quality Assurance Manager to develop a documented procedure for corrective and preventive action, and to co-ordinate the investigation of customer complaints and routine analysis of non-conformance. The Quality Assurance Manager shall also devise documented procedures for controlling any customer complaints that are received.

2.2 In the event of customer complaint, it shall be the responsibility of the Managing Director to determine whether an advisory notice should be issued or a product recall is necessary.

3.0 REQUIREMENTS

3.1 Corrective and preventive actions shall be undertaken by reviewing available production, quality control data and customer complaints with a view to detecting the causes of non-conformance and improving manufacturing methods accordingly.

3.2 Investigations will consider the need to analyse, *inter alia*, raw materials and their specifications, production processes, batch related concessions, personnel training and inspection test and release procedures.

3.3 The procedure shall allow for reviews of corrective and preventive actions to be carried out in order to ensure that the action has been effective.

3.4 Preventive and corrective actions shall be subject to Management Review procedures.

3.5 All customer complaints shall be filed separately from other corrective action documentation

and shall be clearly marked "CUSTOMER COMPLAINTS"

3.6 If any customer complaint is not followed by corrective action, the reason shall be recorded.

4.0 RECALL AND ADVISORY NOTICES

4.1 The Company shall establish comprehensive written advisory notice and product recall procedures. These shall be capable of immediate implementation upon receipt of written authorisation ***by the Managing Director***.

4.2 In response to the findings of the investigation the Company will:

- Notify the complainant of the outcome of the investigation and make any necessary reparation.
- Decide whether the problem may have affected other products and / or customers.
- Where others may be affected decide whether a recall or advisory notice is appropriate (this will depend on both the nature and the level of risk presented by the defect or non-conformity.
- Initiate any changes or additional controls / monitoring necessary to prevent a recurrence.

4.3 In each case the procedures shall be designed to this will ensure that notice includes the following information:

- The type of product and the batches affected.
- The nature of the defect and, if possible how this may be recognised.
- The nature and extent of any risk to the user and / or the patient.
- The action to be taken and the rationale for such action.

4.4 The recall procedure shall also specify:

- The system to be used by the organisation to prevent the distribution of other affected batches.
- The regulatory authority to be informed.

- The method of recording returns and reconciling these with production and distribution records.

- Quarantine facilities for returned product.

4.5 When product is further distributed by a third party the company will make every effort to ensure that traceability is maintained through the distribution train.

4.6 A file will be maintained for each contract customer with details of personnel to be contacted; this will include the facility for contact outside normal hours.

4.7 All reports of defects, failures or non-conformities in distributed product will be recorded in customer complaint files.

4.8 These will be reviewed on a regular basis by ***Management with Executive Responsibility during management reviews.***

4.9 Where a third party carries out the investigation off site, a copy of the investigation report will be held at the manufacturing site.

4.10 Where applicable an Advisory Note shall be issued to provide information and/or advice on a particular product after the results of a product investigation are known.

4.11 Where the results highlight potential dangers to customers a recall Notice shall be issued to all customers of the investigated product, or all sold products from a particular batch.

5.0 RELATED PROCEDURE

5.1 Corrective/preventive action procedure QP 024

5.2 ***Medical Device Vigilance System & Advisory Note and Recall Procedure for CE Marked Products*** QP 025

5.3 USA Complaint and Medical device Reporting Procedure ***QP 035***

5.4 Complaint Files ***QM 033***