SCOPE

This procedure is established to describe the system used within the company for the control of non-conforming product or procedure/process, corrective and preventive actions, and associated negative affects or risk analysis. 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 each process owner to ensure that non-conforming items within that process are controlled as per this procedure. It is the responsibility of all personnel to ensure that they comply with this procedure and associated documents.

There are two levels of internal non-conformance within the companies. Major non-conformances are those affecting the stock and the customers and would result in the creation of a QC21 form to investigate the non conformance.
Minor non-conformance are those that are created to improve the running of the company.

ALL non conformance issues must contain reasoning to explain why the non conformance is or is not a vigilance issue.

PROCEDURE

This procedure defines the system in operation within the company for the non conformance, corrective & preventive actions.
It is the responsibility of the ISO Controller to ensure that this procedure is adhered to. It is the responsibility of all the staff to ensure that the procedure is complied with.

OBJECTIVES

It is the Objective of this VOP to demonstrate the processes involved, in the companies, in relation to the Non conformance, corrective & preventive actions.

MAJOR INTERNAL NON-CONFORMANCES

All Major non conformances will result in the filling in of a QC21 form. There is a section on the QC21 form that assesses the risk analysis of the use of the form, and any changes or updates that result from the utilisation of the form. A Risk Review box will be present that asks the user to **"**Confirm action does not have negative affects and/or risks to any other part of the ISO system. "
This results in a more comprehensively investigated, monitored and resolved Non Conformance.

PRODUCT NON-CONFORMANCES

All products undergo an inspection and / or test process. When product is found to be incorrect to the required specification, then it is subject to a Quarantine/ Hold process. These products are reviewed on a regular basis, with the results and subsequent actions, documented. Any Major issues are reported on a QC21 form.

Intrastats item barcode tracking and scanning to orders, prevents non conforming products being shipped to the end customers.

When we return products or components to the supplier, this triggers a Management Review of the returned items / shipment.

Every two months the managing director gets an Issue to check if any Post Market Surveillance reviews are due, of anything manufactured on site. VM3COP27.11. During a PMS review, if any issues are present, a non conformance follow up action can be raised.

PRODUCT FAILURES

Process ID 7849 Review Product Failures New Codes, Task ID 750. Reviews all product part numbers, and highlights any new fault codes entered. These are reviewed to tidy up the Engineer description into a clean fault code, and determine if the fault is either a Fault, a User Error or a No Fault Code.

For New fault codes, if it is one of our products, it will highlight the range needs the risk/s reviewing.

If it is found to be a serious Non conformance the Vigilance reporting should be followed (VOP19) including a QC 21 QC12 and QC 44 forms.

NON-CONFORMANCE TO SYSTEM

During Audits, between audits or at management or stock meetings, non-conformances to the system may be found. For minor non-conformances a non conformance issue is raised. For major non-conformances a QC21 form is raised and added to a non conformance issue.
This is treated in the same way as a non-conformance during an Audit. Major and Minor non-conformances highlighted by BSI are all classed as Majors as far as the system is concerned.

ACTIONS / CORRECTIVE ACTIONS

The significance of quality problems will be evaluated in terms of their potential impact on such aspects as production costs, quality costs, product performance, reliability, safety and customer satisfaction. The relationship of cause and effect of non-conformance will be investigated. All potential causes will be considered, and important variables affecting non-conformance will be identified. Such investigations and analyses will determine the root cause of the problem before preventive actions are determined. A risk assessments will be carried out, to ensure the risk is managed and the solution does not cause any risk.

These findings will be documented and reported to the appropriate persons. Permanent changes brought about by corrective actions will be recorded.

Where product has been found faulty at goods-in, then the manufacturers and suppliers will be informed and inspection / testing will be monitored until such time as the problem has been corrected.

All preventive actions as defined by the company are inherent in the design and development process, together with any appropriate manufacturing and systems processes. Any actions proposed will be monitored and documented.
Where appropriate, or where required by such as Customer Complaints, Internal problems etc., corrective actions will be addressed and implemented. Where the Sales team or other personnel highlight potential problems, then these will be reviewed and analysed for their possible impact on products or services.
When a problem is highlighted, the Managing Director will be informed as to all possible scenarios so that all the relevant information is available to enable the correct decision to be made.

The decision made, may be one that has a direct bearing on the design of the product or on the integrity of the service provided. Where this is the case then all relevant personnel will input to the problem.
Should the actions taken, whether corrective or preventive, have impacts on Customer satisfaction, then the Customer will be immediately informed and actions followed-up to ensure full satisfaction. Subsequent actions such as design modifications will be entered into the design file VOP 17, (CE file where appropriate) and all records amended.

All records pertaining to Non-conformances, Corrective actions, Risk assessments and internal investigations will be held forever on Intrastats and any paperwork kept for a minimum of 11 years in Archives.

ALL NON CONFORMANCE ISSUES must contain reasoning to explain why the non conformance is or is not a vigilance issue.

MINOR INTERNAL NON-CONFORMANCES
These are non-conformances that are found during the everyday working of the company and are generated by all staff within the company. These can be anything that is an inconsistency or error / mistake. They are recorded so that we can see areas that require help or more training. We can see over time if the corrective steps we have put in place have been effective.

Error logging that relates to customer orders can be done within the system, on the Invoice or Order as they are found and corrected. Also when credits are processed. This can be found on the Invoice Page under ‘Log Error on Order or Invoice’.

When an error or mistake is discovered that goes beyond the error logging level. A non Conformance Issue is generated, through Intrastats issues under the Non-conformance heading. This is a private issue so only directors can read it.

Every 3 months a non conformance review is carried out, and where relevant a report sent to staff. This can details any problems reported and includes the Error Logging figure. At this time any further corrective action can be implemented. Any issue that need to be dealt with more quickly or immediately can be dealt with as they come in, by management.
At this time a review should be carried out to see if there are any recurring issue that have not been solved.

If an internal non conformance causes an outside party, supplier or customer to take remedial action or is unsatisfied with our service an official QC 21 form Document ID74573 shall be completed.

PREVENTATIVE ACTIONS

Preventative actions are identified through:

- Intrastats self monitoring and automatic issues.
- Constant reviews of Customer Complaints and Feedback meetings and issues.
- Regular reviews of Non Conformances
- Employee suggestions – via the logged issues systems.
- Purchase and returns reviews.
- Analysis of data reviews.
- Sales warnings reviews.
- Post Market Surveillance on products.

All Issues identified should be logged in the Issue system under the appropriate meeting agenda header. Any action taken or decision of action to be taken should be logged inside the Issue created, risk assessments will be carried out where needed.

As per the normal Issue system only the person whom identified the Preventative Action Required is able to fully close the Issue, once its been completed. Or It can be completed of while holding a full meeting.

Computer systems are the central core of most Current Preventative Actions. Including but not limited to:

Any preventative action taken will initiate a Risk analysis and review of the Risk affect.

STOCK PROCESSING

Digital training records – which work out if an employee can be allocated a production job or perform QA, unless they have been trained and signed off.

Document updates – documents are digitally linked to processes and training records. Many processes are halted before they can begin unless the operator is both, trained in and read, the latest version of any relevant documentation.

CONTRACT REVIEW

Prices are in the Intrastats system and used by accountants for the yearly figures. Quotations, orders, invoices, price lists and digital report screens, all refer to the main table so there are no inconsistencies.

Orders are entered into the Intrastats system, the order is flagged as unchecked until its has gone through the Intrastats checking system. Where another member of staff compares the entered data to the customer paperwork and existing customer memos. As this is a human error point in the process.

All sales order related paperwork is attached to the customer order in Intrastats, meaning these are easily retrievable.

Order picking – Goods are picked to the customer order by scanning the barcode where the computer checks the product:

- If it needs QA has it been
- Is the item sellable
- Has the stock expired
- Is the item on the customers order
- Have enough items been scanned
- Have too many items been scanned
- Has the order been checked

Sending of invoices is via email, direct to users via the send invoices procedure.

By reviewing users requests, the non-conformance and the weekly rolling tasks / audits reviews. We provide more ways of preventing unwanted outcomes being added to the system.

The Active List screen is digital and reviewed by both the Warehouse and the Office constantly / daily. The systems check which orders can be picked, which customers orders cannot be picked and when the customer was last informed of the status of their order.

Any customer change of requirements, will disable the order on the Active List, so the Order is prevented from being processed.

PURCHASE ORDERS

All items ordered, are ordered by part number and pre agreed supplier reference codes, so no confusion on purchase order requests / specifications. All Purchase orders are processed in Intrastats and all related paperwork is attached to the purchase order.

BARCODE TRACKING

All items including customer repairs, are tracked via the barcode system. Each barcode is tracked, as it get processed through the building.
The barcode is aware if its a component of a bigger item, if its requires QA or further processing before being ready for sale. The barcode will stop the item being picked for orders, if it does not match the order or is not ready for sale.

Barcodes on stock that have failed QA, get flagged up on a monthly reports. So percentages of failures, of types of item can be calculated. This can potentially prevent other non conformities in other items and where the items are.