SCOPE

This procedure defines the system in operation at the company for carrying out planned internal audits, and / or reviews, necessary to verify compliance with all aspects of the defined quality program. 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. To oversee all requirements of this procedure, with delegated nominees adding to the audit team if and where necessary.

INTERNAL AUDITS

Overview |Audit – carried out when due and triggered by the system. The audit calendar can be view in Intrastats ISO → Route Map.
Each section of the company's system, as described in the manual, is audited at least once per annum. Further audits are dependant upon previous results. Product audits will also be performed as dictated by company and regulatory needs. The auditor will diligently check that the procedures in operation are being complied with, and are suitable and effective. Checklists may be generated for use in the audit, and would therefore form the basis of the audit records, cognisance of previous audit results is taken when generating any checklists.

Where corrective actions are needed as a result of the audit, Create a follow up / related Issue linked to the primary audit, which includes a time for Completion, Immediate Action Plan, Corrective Action Plan, Corrective Action, Confirmation of Resolution. If its a major / critical non conformance complete form QC 21.

Subsequent follow-ups will take place within one week of these effective dates, to assess compliance. The auditor will formally close out the audit after having been assured that follow-up actions have been satisfactorily completed. All results will are recorded in the issue's and linked issues.

Overview Mini-audit – Intrastats generates Issues when an audit is due, it will be carried out within 2 months of being generated, the completed checklist will be uploaded to the issue by the person responsible for carrying out the audit. Any non conformance's or corrective actions shall be tracked by related Issues to the original Issue.
Overview audit issues shall be reviewed by management before being completed.

History of audits can be retrieved by pulling up the history of the Rolling Issue, or the appropriate header in intrastats.
Each overview Audit document is tagged in the Admin panel as to which sections of the QMS system the audit relates to.

Mini Audit – Each underlying process, depending on the risk and type of process, can be allocated a Rolling Audit Issue. As each process has an allocated employee, any other employee can perform a mini audit. Most Mini audits contain instructions on carrying out the audit, within the issue, generated.

Weekly Management review, of rolling Tasks and Audits, will either close the Mini Audit, or generate further actions if required. Further action Issues, are linked to the original audit Issue, and tracked until completion.
History of a Mini Audits / associated tasks are linked to every mini audit, and available from the related Issues.
On completion of the weekly management review, the Task / Audit completion history screen is displayed, where any outstanding Issues from previous tasks / audits are highlighted for re-review.

Procedures will be periodically assessed for possible changes needed. NB may need approval of Assessment Body.

BOARD MEETING MANAGEMENT REVIEW
Process 7846, Rolling Task 746. Senior management at the official Board Meetings, together with other management staff, as deemed appropriate, will review the System and its processes at least once every year +/- 2 Months. The review agenda will constitute, as a minimum, the following points:

a. Follow-up actions from previous reviews.
b. Customer feedback.
c. Results of internal audits.
d. Process and product performance.
e. Preventive and corrective actions.
f. Possible system changes.
g. Recommendations or improvement.
h. Any other business

In addition, each of the following points, as a minimum, will be addressed:

1. Contract review, Picking, Packing and Despatch
2. Purchasing controls
3. Supplier, subcontractor performance
4. Storage and Stock control
5. Customer complaints
6. Calibration
7. Documentation and records
8. Training
9. Internal audits and corrective actions
10. Review of responsibilities
11. Resources required
12. New products etc.
13. Quality planning
14. Achievement of Quality Policy

15. Advisory notices and recalls
16. Vigilance system (Complaints, Repair levels, Surveillance)
17. Changes to the Management system
18. Changes to CE marked products

The review will be minuted, a plan of action, in the form of issues will be generated from it. Activities undertaken in the plan of action will be timely, and subsequently verified by the Managing Director.

Weekly Management Reviews

Where possible a weekly review of **ALL** tasks and audits, across all departments and areas is undertaken, but never more than 3 weeks apart in special circumstances.
As per Mini Audits above.
Weekly Management review of rolling Tasks and Audits will either close the Mini Audit, or generate further actions if required, further action Issues are linked to the original audit issue, and tracked until completion.
History of a Mini Audit / associated tasks are linked to every mini audit, and available from the related Issues.
On completion of the weekly management review, the Task / Audit completion history screen is displayed, where any outstanding Issues from previous tasks / audits are highlighted for re-review.

Product Reviews Post Market Surveillance

Manufactured products – Each range shall be reviewed once per year + 2 months depending on the timing of the triggering Issue, to perform the Product review (Task ID 50)
Each product type will have a post market surveillance report created, as per VM3COP27.11
Stock References will be confirmed, as included in the review:

- All related suppliers will be confirmed, and checked that the supplier review is up to date.
- Sales Information will reviewed.
- Country Sales will be reviewed.
- Returns and QA Failures will be reviewed. (Note due to the size and quantity of information within the Returns and QA reviews, a summary is listed, in the Final Post Market surveillance report).
- Any design changes will be reviewed.
- Instruction manual changes will be reviewed.
- Labels will be reviewed.
- Other Documentation changes will be reviewed.

All internal Issues relating to the product ranges will be reviewed, (again due to the quantity of information contained within the Issue review, only the ID and subject will be listed in the Final Post Market surveillance – however during the review and afterwards the entire issue history is available).
A web search for Clinical / FDA reports will be performed to see if there are any unknown risks (maybe with competitors products) or if the technology is outdated.

Issues created during the review will be evaluated to see if the Risk file requires updating.

Management Product Reviews General

Rolling Issues to review the 'New Repair Code' information across all products supplied. Both in house produced items or those supplied by other manufacturers will appear on this list. The report screen displays any new type of fault as discovered by QA / Returns engineers. During the review the repair code is either linked to a clean code, or a new clean code is produced.
If its an in house product, and there is a new clean code, an entry into the Risk file is made (now automatically), for further investigation to evaluate the potential new risk presented. Rolling Task ID 750, Rolling Audit 751.

QA Reviews rolling task 727 Rolling, Audit 729. All the previous months QA is reviewed, when there is a high percentage of failures a non conformance issue is raised to examine further the potential problem.

Sub Processes Linked to VOP 13

Share Holder

Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
7834 Shareholder review of the Financial position of the Companies	Financial Review	User Training	733 Share Holder	769 Managing Director	1	1	1	Task 1M Audit 3M
7862 Review The Audit Calendar Screen	Review The Audit Calender Screen	User Training		173 Managing Director	1	1	1	Audit 12M

Managing Director

Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
22 Ensure the company policys are still current and upto date	Company Policys	22684 VM3COP00.00 Viamed Quality Statement policy and objectives	300 Managing Director		1	1	1	Task 12M
23 Ensure the company Objects are still current and upto date	Company Objectives	22684 VM3COP00.00 Viamed Quality Statement policy and objectives 22062 VM3COP00.00	300 Managing Director					Task 12M

		VST Quality Statement policy and objectives 13310 VST Company Policy and Objectives 22429 Viamed Top Level Quality Objectives						
26 Overview of the Company using various data Reporting Screens	Company Resources	User Training	114 Managing Director		1	1	1	Task 1M
27 To review and Close all automatic rolling Issues. Including all rolling tasks and audits	Management Reviews And Quality Audits	16995 VM3COP27.17 Complete Auto_calender Issues	290 Managing Director	775 Company Secretary	1	1	1	Task 1W Audit 6M
38 Management oversight of Internal Tasks and Audits Issue(s). Review the responses to Tasks and Audits. ensure they are being full filled and completed.	Audits Up to Date and Confirm next years Audit schedule	User Training	730 Managing Director		0	0		Task 12M
55 Business Continuity Plan	Business Continuity Plan	9546 VM3COPxx Business Continuity Plan	266 Managing Director		1	1	1	Task 12M
5877 To review the numbers of various departments. Showing increasing / reducing staff requirements	Review Company Data	Responsibility Allocation : Managing Director	114 Managing Director	561 Company Secretary	0	0		Task 1M Audit 12M
6904	Sales And Marketing	Responsibility Allocation :						

	Internal sales	Managing Director						
6944	Stock Meeting	User Training						
7070 To discuss any problems, to assess work load and staffing. To review issues.	Management Review	User Training	83 Managing Director		1	1	1	Task 3M
7846 To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13	ISO System Management Review	22594 Management Review Minutes 20xx	746 Managing Director		1	1	1	Task 12M
7848 To Review the Scope of the ISO 9001 / ISO 13485 Standards	Review ISO Scopes	22645 Viamed ISO 13485:2016 Scope 22291 Viamed ISO 9001:2015 Scope 22301 VST ISO 9001:2015 Scope 13379 VOP 02 Personnel and Responsibility	749 Managing Director		1	1	1	Task 12M
ISO Controller								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
24	Compliance ISO Standards	User Training						
28 Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.	Supplier Review	13383 VOP 05 Supplier Control	15 Managing Director	610 Company Secretary	1	1	1	Task 12M Audit 12M
5887 To Keep Products and Services up-to date with	Review ISO/EN Documents	User Training	235 Managing Director		2	2	4	Task 3M

current regulations and standards								
5889 To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits	Audit And Task - Audit	Responsibility Allocation : ISO Controller	290 Managing Director		1	1	1	Task 1W
6828 To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement.	Non Conformance Issues	21314 vop VM3COP20.11 Non-Conformances	88 Company Secretary	284 Managing Director	1	1	1	Task 1M Audit 12M
6865	Non Conformance Effectiveness	Responsibility Allocation : ISO Controller						
6866 Review the Internal Process and	Internal Process Verification	8948 Internal process verification	55 Managing Director		1	1	1	Task 12M

Verification`s are suitable for the current standards	Complete Systems Review							
6871 Not yet Applied Rolling Issue to see if we should apply this standard in the future	ISO14001 Environmental management systems	User Training	748 Managing Director		1	1	1	Task 12M
7071 The process by which re view and risk assess all product files, check that no Products / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.	Post Market Surveillance	User Training	50 Managing Director	14 Company Secretary	2	4	8	Task 2M Audit 12M
7093 Review of outstanding Audits	BSI Audits Calander	User Training	725 Managing Director		1	1	1	Task 12M
7172	CE Technical Files	User Training	50 Managing Director					Task 2M
7829 Complete Systems Review	Complete Systems Review	User Training	726 Managing Director		1	1	1	Task 12M
Product Controller								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
5854 To update and maintain the Stock FAQ list	Stock FAQ Admin List	User Training	231 Director 3 (Steve)	374 Managing Director	1	1	1	Task 1M Audit 3M

6833	VIAMED Management Meeting MDA Recalls	Responsibility Allocation : Product Controller
6834	Additional Purchase Orders	Responsibility Allocation : Product Controller
6836	Research and Development rnd	Responsibility Allocation : Product Controller
6920	VIAMED Sales And Marketing Price Lists UK	Responsibility Allocation : Product Controller
6924	VIAMED Sales And Marketing Price Lists Export	Responsibility Allocation : Product Controller
6935	VIAMED Sales And Marketing Products to be Marketed	Responsibility Allocation : Product Controller
6936	VIAMED Sales And Marketing NHS Supplies Future Technology	Responsibility Allocation : Product Controller
6941	VIAMED Sales And Marketing New Potential Products	Responsibility Allocation : Product Controller
7039	Provision of Resources	Responsibility Allocation : Product Controller
7043	Planning of product realization	Responsibility Allocation : Product Controller
7187	VIAMED Board Directors Meeting Profiability	Responsibility Allocation : Product Controller

7196	VIAMED Board Directors Meeting Stock Levels	Responsibility Allocation : Product Controller						
Sales Controller								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
57 To Review Memos on Stock references tagged as Temporary	Temporary Stock Notices	User Training	207 Director 3 (Steve)	206 Managing Director	1	1	1	Task 1M Audit 3M
7204	VIAMED Board Directors Meeting Distributor Issues	Responsibility Allocation : Sales Controller						
Warehouse Team Leader								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
7138 To review any new QC 21 Forms	Non Conformance Issues Any New QC21 Forms	User Training	795 Managing Director	796 Company Secretary	1	1	1	Task 1M Audit 12M
Office Team Leader								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
7090	Office Procedures	Responsibility Allocation : Office Team Leader						
Humanmed Controller								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
7670 Review of Humanmed sales and orders and	Humanmed general Issues	User Training	611 Office Processes		1	1	1	Task 1M

clear any duplicates or problems.								
7782 Remove Started But Not Used Order Numbers from intrastats.	Remove Started But Not Used Order Numbers	User Training	770 Managing Director		1	1	1	Task 3M
EX Sales Controller								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
6886	VIAMED Sales And Marketing Sales Viamed Medical Export	Responsibility Allocation : EX Sales Controller						
6887	VIAMED Sales And Marketing Sales Viamed Automotive Export	Responsibility Allocation : EX Sales Controller						
OEM Sales Controller								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
7808 To find and Tag any sales that are removed from commissions, as they are break even products for relationships purposes	Ensure All Invoice Correctly Tagged	User Training	670 Managing Director	704 Director 3 (Steve)	1	1	1	Task 1M Audit 3M
Audits								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
7714 To carry out Audit 01 Picking Packing Viamed	Audit 01 Picking Packing Viamed	User Training		24 Managing Director	1	2	2	Audit 12M

7715 To carry out Audit 02 Contract Review Viamed	Audit 02 Contract Review Viamed	User Training		36 Company Secretary	1	2	2	Audit 12M
7716 To carry out Audit 03 Design Control Viamed	Audit 03 Design Control Viamed	User Training		22 Company Secretary	1	2	2	Audit 12M
7717 To carry out Audit 05 Purchasing Suppliers Viamed	Audit 05 Purchasing Suppliers Viamed	User Training		37 Company Secretary	1	2	2	Audit 12M
7718 To carry out Audit 06 Calibration Viamed	Audit 06 Calibration Viamed	User Training		20 Company Secretary	1	2	2	Audit 12M
7719 To carry out Audit Audit 07 Handling And Storage Viamed	Audit 07 Handling And Storage Viamed	User Training		25 Company Secretary	1	2	2	Audit 12M
7720 To carry out Audit 08 Training Viamed	Audit 08 Training Viamed	User Training		10 Managing Director	1	2	2	Audit 12M
7721 To carry out Audit 09 Goods Inward And Product Identity Viamed	Audit 09 Goods Inward And Product Identity Viamed	User Training		170 Company Secretary	1	2	2	Audit 12M
7722 To carry out Audit 10 Documentation Control Viamed	Audit 10 Documentation Control Viamed	User Training		27 Company Secretary	1	2	2	Audit 12M
7723 To carry out Audit 10b Process Verification Viamed	Audit 10b Process Verification Viamed	User Training		3 Company Secretary	1	2	2	Audit 12M
7724 To carry out Audit 11 Repairs And	Audit 11 Repairs And Service	User Training		171 Company Secretary	1	2	2	Audit 12M

Service Viamed	Viamed						
7725 To carry out Audit 12 CE Files Viamed	Audit 12 CE Files Viamed	13387 VOP 07 Stock Control / Handling and Storage	16 Company Secretary	1	2	2	Audit 12M
7726 To carry out Audit 14 Complaints And Corrective Actions Viamed	Audit 14 Complaints And Corrective Actions Viamed	User Training	30 Company Secretary	1	2	2	Audit 12M
7727 To carry out Audit 15 Production Viamed	Audit 15 Production Viamed	User Training	28 Company Secretary	1	2	2	Audit 12M
7728 To carry out Audit 17 Internal Audits Viamed	Audit 17 Internal Audits Viamed	User Training	11 Company Secretary	1	2	2	Audit 12M
7729 To carry out Audit 19 Health And Safety Viamed	Audit 19 Health And Saftey Viamed	User Training	13 Company Secretary	1	2	2	Audit 12M
7730 To carry out Audit 20 Process Verification To Management Viamed	Audit 20 Process Verification To Managment Viamed	User Training	172 Company Secretary	1	2	2	Audit 12M
7731 To carry out Audit 21 Audit Of Audit Viamed	Audit 21 Audit Of Audit Viamed	User Training	173 Managing Director	1	2	2	Audit 12M
7732	Audit 22 Post Market Survellance Viamed	User Training	14 Company Secretary				Audit 12M
7733 To carry out Audit 23 Analysis Of Data Viamed	Audit 23 Analysis Of Data Viamed	User Training	43 Company Secretary	1	2	2	Audit 12M
7762 To carry out Audit 01 Picking Packing VST	Audit 01 Picking Packing VST	User Training	194 Company Secretary	1	2	2	Audit 12M

7763 To carry out Audit 02 Contract Review VST	Audit 02 Contract Review VST	User Training		187 Company Secretary	1	2	2	Audit 12M
7764 To carry out Audit 03 Design Control VST	Audit 03 Design Control VST	User Training		193 Company Secretary	1	2	2	Audit 12M
7765 To carry out Audit 05 Purchasing Suppliers VST	Audit 05 Purchasing Suppliers VST	User Training		190 Company Secretary	1	2	2	Audit 12M
7766 To carry out Audit 06 Calibration VST	Audit 06 Calibration VST	User Training		182 Company Secretary	1	2	2	Audit 12M
7767 To carry out Audit 07 Handling And Storage VST	Audit 07 Handling And Storage VST	User Training		178 Company Secretary	1	2	2	Audit 12M
7768 To carry out Audit 08 Training VST	Audit 08 Training VST	User Training		184 Managing Director	1	2	2	Audit 12M
7769 To carry out Audit 09 Goods Inward And Product Identity VST	Audit 09 Goods Inward And Product Identity VST	User Training		174 Company Secretary	1	2	2	Audit 12M
7770 To carry out Audit 10 Documentation Control VST	Audit 10 Documentation Control VST	User Training		183 Company Secretary	1	2	2	Audit 12M
7771 To carry out Audit 10b Process Verification VST	Audit 10b Process Verification VST	User Training		177 Company Secretary	1	2	2	Audit 12M
7772 To carry out Audit 11 Repairs And Service VST	Audit 11 Repairs And Service VST	User Training		179 Company Secretary	1	2	2	Audit 12M
7773 To carry out Audit 12 CE Files VST	Audit 12 CE Files VST	User Training		176 Company Secretary	1	2	2	Audit 12M
7774 To carry out Audit 14	Audit 14 Complaints	User Training		189 Company	1	2	2	Audit 12M

Complaints And Corrective Actions VST	And Corrective Actions VST			Secretary				
7775 To carry out Audit 15 Production VST	Audit 15 Production VST	User Training		175 Company Secretary	1	2	2	Audit 12M
7776 To carry out Audit 17 Internal Audits VST	Audit 17 Internal Audits VST	User Training		191 Company Secretary	1	2	2	Audit 12M
7777 To carry out Audit 19 Health And Safety VST	Audit 19 Health And Saftey VST	User Training		186 Company Secretary	1	2	2	Audit 12M
7778 To carry out Audit 20 Process Verification To Management VST	Audit 20 Process Verification To Managment VST	User Training		181 Company Secretary	1	2	2	Audit 12M
7779 To carry out Audit 21 Audit Of Audit VST	Audit 21 Audit Of Audit VST	User Training		192 Managing Director	1	2	2	Audit 12M
7780 To carry out Audit 22 Post Market Surveillance VST	Audit 22 Post Market Survellance VST	User Training		180 Company Secretary	1	2	2	Audit 12M
7781 To carry out Audit 23 Analysis Of Data VST	Audit 23 Analysis Of Data VST	User Training		185 Company Secretary	1	2	2	Audit 12M
Office Processes								
Process Scope	Brief Description	Responsibility/Procedure/Training	Task	Audit	Risk	Freq	Overall	Action
7754 Ensure procedures are relevant and up to date, update as requred	Ensure Procedures Are Up-to-date	User Training	594	595	1	1	1	