

| <b>VOP</b>                          |               |  |                |
|-------------------------------------|---------------|--|----------------|
| <b>Viamed Operating sub Process</b> |               |  |                |
| <b><u>PROCESS MONITORING</u></b>    |               |  |                |
| Created:                            | 27/03/06      | VOP 13   | <b>Issue 1</b> |
| Revised:                            | 06 March 2018 | Viamed Ltd ISO13485:2016: 8.4, 8.1, 5.6.2 Review input, 4.1.3, 8.2.4, 5.6.1, 8.2.1, 8.2.5, VST Ltd ISO9001:2015: 6.2.1, 9.2.1, 9.1.3, 8.5.5, 9.3.2, 9.2.2, 9.3.1, 9.1.2, 9.1.1 | Page 1 of 16   |
| <b><u>Charts 07, 16, 19, 26</u></b> |               |  |                |

## **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.

## **DATA AND INFORMATION ANALYSIS**

See VOP 15 data and information analysis.

## **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 18.

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 will consist of analysis intrastats data reports, and where possible using statistical techniques.

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

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|--|--|
| 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 levels, Surveillance) | 16. Vigilance system (Complaints, Repair |
| 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 Managing Director            | Review The Audit Calender Screen | User Training                     |                  | 173 Managing Director | 1    | 1    | 1       | Audit 12M        |

| 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           | Company Objectives | 22684 VM3COP00.00 Viamed Quality Statement policy                | 300 Managing Director |       |      |      |         | Task 12M |

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| upto date   |   | and objectives<br>22062<br>VM3COP00.00<br>VST Quality<br>Statement policy<br>and objectives<br>13310 VST<br>Company Policy<br>and Objectives<br>22429 Viamed Top<br>Level Quality<br>Objectives |                             |                             |   |   |   |                            |
| 26 Overview of the Company using various data Reporting Screens   | Company Resources                                       | User Training   | 114<br>Managing<br>Director |                             | 1 | 1 | 1 | Task<br>1M                 |
| 27 To review and Close all automatic rolling Issues. Including all rolling tasks and audits   | Management Reviews And Quality Audits                   | 16995<br>VM3COP27.17<br>Complete<br>Auto_calender<br>Issues   | 290<br>Managing<br>Director | 775<br>Company<br>Secretary | 1 | 1 | 1 | Task<br>1W<br>Audit<br>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<br>Managing<br>Director |                             | 0 | 0 |   | Task<br>12M                |
| 55 Business Continuity Plan   | Business Continuity Plan                                | 9546 VM3COPxx<br>Business<br>Continuity Plan  | 266<br>Managing<br>Director |                             | 1 | 1 | 1 | Task<br>12M                |
| 5877 To review the numbers of various departments. Showing increasing / reducing staff  | Review Company Data                                     | Responsibility Allocation :<br>Managing Director  | 114<br>Managing<br>Director | 561<br>Company<br>Secretary | 0 | 0 |   | Task<br>1M<br>Audit<br>12M |

requirements

|  |                                    |  |                       |                       |      |      |         |        |               |
|--|------------------------------------|--|-----------------------|-----------------------|------|------|---------|--------|---------------|
| 6904   | Sales And Marketing Internal sales | Responsibility Allocation : 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   | Review                             | User Training  | 235                   |                       | 2    | 2    | 4       | Task   |               |

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| Products and Services up-to date with current regulations and standards   | ISO/EN Documents              |  | Managing Director     |                       |   |   |   | 3M                |
| 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.  | Non Conformance Issues        | 21314 vop VM3COP20.11 Non-Conformances     | 88 Company Secretary  | 284 Managing Director | 1 | 1 | 1 | Task 1M Audit 12M |
| Review history of non conformances and see if there has been any improvement.   |                               |  |                       |                       |   |   |   |                   |
| 6865  | Non Conformance Effectiveness | Responsibility Allocation : ISO Controller |                       |                       |   |   |   |                   |

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| 6866 Review the Internal Process and Verification's are suitable for the current standards  | Internal Process Verification Complete Systems Review | 8948 Internal process verification | 55 Managing Director  |                      | 1    | 1    | 1       | Task 12M          |
| 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 Product Controller   | Complete Systems Review                               | User Training                      | 726 Managing Director |                      | 1    | 1    | 1       | Task 12M          |
| Process Scope   | Brief Description                                     | Responsibility/Procedure/Training  | Task                  | Audit                | Risk | Freq | Overall | Action            |
| 5854 To update  | Stock FAQ   | User Training                      | 231                   | 374                  | 1    | 1    | 1       | Task              |



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|---------------------------------|---|--|--------------------|-------------------|-------------|
| and maintain the Stock FAQ list | Admin List  |  | Director 3 (Steve) | Managing Director | 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  | Responsibility Allocation :                    |                    |                   |             |

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| 7196   | Directors Meeting Profitability                   | Product Controller                             |                        |                       |      |      |         |                   |
|  | 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  | Humanmed  | User Training                                  | 611                    |                       | 1    | 1    | 1       | Task              |

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|---|---|---|-----------------------|------------------------|------|------|---------|------------------|---------|
| of Humanmed sales and orders and clear any duplicates or problems.  | general Issues  |   | Office Processes      |                        |      |      |         |                  | 1M      |
| 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 Audits | Ensure All Invoice Correctly Tagged                       | User Training                                   | 670 Managing Director | 704 Director 3 (Steve) | 1    | 1    | 1       | Task 1M Audit 3M |         |
| Process Scope   | Brief Description   | Responsibility/Procedure/Training               | Task                  | Audit                  | Risk | Freq | Overall | Action           |         |
| 7714 To carry out Audit 01 Picking  | Audit 01 Picking Packing                                  | User Training                                   |                       | 24 Managing Director   | 1    | 2    | 2       | Audit 12M        |         |

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

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

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

|  |   |                                   |      |       |      |      |         |           |
|--|---|-----------------------------------|------|-------|------|------|---------|-----------|
| 7774 To carry out Audit 14 Complaints And Corrective Actions VST       | Audit 14 Complaints And Corrective Actions VST  | User Training                     |      | 189   | 1    | 2    | 2       | Audit 12M |
| 7775 To carry out Audit 15 Production VST                              | Audit 15 Production VST                         | User Training                     |      | 175   | 1    | 2    | 2       | Audit 12M |
| 7776 To carry out Audit 17 Internal Audits VST                         | Audit 17 Internal Audits VST                    | User Training                     |      | 191   | 1    | 2    | 2       | Audit 12M |
| 7777 To carry out Audit 19 Health And Safety VST                       | Audit 19 Health And Safety VST                  | User Training                     |      | 186   | 1    | 2    | 2       | Audit 12M |
| 7778 To carry out Audit 20 Process Verification To Management VST      | Audit 20 Process Verification To Management VST | User Training                     |      | 181   | 1    | 2    | 2       | Audit 12M |
| 7779 To carry out Audit 21 Audit Of Audit VST                          | Audit 21 Audit Of Audit VST                     | User Training                     |      | 192   | 1    | 2    | 2       | Audit 12M |
| 7780 To carry out Audit 22 Post Market Surveillance VST                | Audit 22 Post Market Surveillance VST           | User Training                     |      | 180   | 1    | 2    | 2       | Audit 12M |
| 7781 To carry out Audit 23 Analysis Of Data VST Office Processes       | Audit 23 Analysis Of Data VST                   | User Training                     |      | 185   | 1    | 2    | 2       | Audit 12M |
| Process Scope  | Brief Description                               | Responsibility/Procedure/Training | Task | Audit | Risk | Freq | Overall | Action    |
| 7754 Ensure procedures are relevant and up to date, update as required | Ensure Procedures Are Up-to-date                | User Training                     | 594  | 595   | 1    | 1    | 1       |           |

