# Internal Audit Check list

## DOCUMENT CONTROL

| Created: | 17/May 1995 | **Audit No 10** | VOP 01 |
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| Revised: | 01 September 2020 | | Page 1 of 17 |
| Audit Date | 7 Sept 20 | Auditor Helen Lamb | ISO 4.2 4.2.2 |

Documentation control is being moved from a paper system to Intrastats
Many of the questions asked are now superfluous as the checks are carried out automatically,
and recorded automatically. The hard copies are being replaced and Archived.

| Company / ISO Section | Criteria of ISO Section | Auditor Comments / Issues |
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| VST Ltd ISO9001:2015 10.2.1 | When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered. | Intrastats procedures VOP's management review Regular meetings |
| VST Ltd ISO9001:2015 10.2.2 | The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action. | Intrastats |
| VST Ltd ISO9001:2015 10.3 | **Continual improvement** The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement. | Review meetings Roles + Responsibilities |
| VST Ltd ISO9001:2015 4.4.1 | **Quality management system and its processes** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the | Doc index Route map Intrastats |

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| | quality management system and their application throughout the organization, and shall:<br>a) determine the inputs required and the outputs expected from these processes;<br>b) determine the sequence and interaction of these processes;<br>c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;<br>d) determine the resources needed for these processes and ensure their availability;<br>e) assign the responsibilities and authorities for these processes;<br>f) address the risks and opportunities as determined in accordance with the requirements of 6.1;<br>g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;<br>h) improve the processes and the quality management system | Review meetings |
| VST Ltd<br>ISO9001:2015<br>4.4.2 | **Quality management system and its processes**<br>To the extent necessary, the organization shall:<br>a) maintain documented information to support the operation of its processes;<br>b) retain documented information to have confidence that the processes are being carried out as planned. | Doc index<br><br>Infrastats |
| VST Ltd<br>ISO9001:2015<br>5.1.1 | **General**<br>Top management shall demonstrate leadership and commitment with respect to the quality management system by:<br>a) taking accountability for the effectiveness of the quality management system;<br>b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;<br>c) ensuring the integration of the quality management system requirements into the organization's business processes;<br>d) promoting the use of the process approach and risk-based thinking;<br>e) ensuring that the resources needed for the quality management system are available;<br>f) communicating the importance of effective quality management and of conforming to the quality management system requirements;<br>g) ensuring that the quality management system achieves its intended results;<br>h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;<br>i) promoting improvement;<br>j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.<br>NOTE Reference to "business" in this International Standard | Vops<br>infrastats<br><br>management<br>Review<br><br><br><br>Tasks + Audit System<br><br>Issues |

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| | can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit. | |
| VST Ltd ISO9001:2015 5.2.2 | **Communicating the quality policy** The quality policy shall: a) be available and be maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as appropriate. | Doc index Issues Required reading |
| VST Ltd ISO9001:2015 6.2.1 | The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. The organization shall maintain documented information on the quality objectives | Route map Tasks + Audit System Roles + Responsibilities Infrastructure Issues |
| VST Ltd ISO9001:2015 6.3 | **Planning of changes** When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities. | Management + other Reviews Issues |
| VST Ltd ISO9001:2015 7.1.3 | **Infrastructure** The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology. | Issues + Review meetings |
| VST Ltd ISO9001:2015 7.1.5.2 | **Measurement traceability** When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no | Bar code tracing infrastructure |

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| | such standards exist, the basis used for calibration or verification shall be retained as documented information;<br>b) identified in order to determine their status;<br>c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary. | Calibration index<br>QA<br>Reviews/issues |
| VST Ltd<br>ISO9001:2015<br>7.1.6 | **Organizational knowledge**<br>The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.<br>This knowledge shall be maintained and be made available to the extent necessary.<br>When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.<br>NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.<br>NOTE 2 Organizational knowledge can be based on:<br>a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);<br>b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers) | Doc index<br>procedures<br>&<br>issues + Review meetings |
| VST Ltd<br>ISO9001:2015<br>7.4 | **Communication**<br>7.4 Communication<br>The organization shall determine the internal and external communications relevant to the quality management system, including:<br>a) on what it will communicate;<br>b) when to communicate;<br>c) with whom to communicate;<br>d) how to communicate;<br>e) who communicates. | Intranets<br>VOPs<br>procedures |
| VST Ltd<br>ISO9001:2015<br>7.5.1 | **General**<br>7.5.1 General<br>The organization's quality management system shall include:<br>a) documented information required by this International Standard;<br>b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.<br>NOTE The extent of documented information for a quality management system can differ from one organization to | Doc index<br>procedures VOPs |

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| | another due to:<br>— the size of organization and its type of activities, processes, products and services;<br>— the complexity of processes and their interactions;<br>— the competence of persons. | |
| VST Ltd<br>ISO9001:2015<br>7.5.2 | **Creating and updating**<br>7.5.2 Creating and updating<br>When creating and updating documented information, the organization shall ensure appropriate:<br>a) identification and description (e.g. a title, date, author, or reference number);<br>b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);<br>c) review and approval for suitability and adequacy. | Doc index<br>Intranstarts |
| VST Ltd<br>ISO9001:2015<br>7.5.3 | **Control of documented information** | |
| VST Ltd<br>ISO9001:2015<br>7.5.3.1 | Documented information required by the quality management system and by this International Standard shall be controlled to ensure:<br>a) it is available and suitable for use, where and when it is needed;<br>b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | Doc index<br>Intranstarts |
| VST Ltd<br>ISO9001:2015<br>7.5.3.2 | For the control of documented information, the organization shall address the following activities, as applicable:<br>a) distribution, access, retrieval and use;<br>b) storage and preservation, including preservation of legibility;<br>c) control of changes (e.g. version control);<br>d) retention and disposition.<br>Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.<br>Documented information retained as evidence of conformity shall be protected from unintended alterations.<br>NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information. | Doc index<br>Intranstarts |
| VST Ltd<br>ISO9001:2015<br>8.1 | **Operational planning and control**<br>The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:<br>a) determining the requirements for the products and services;<br>b) establishing criteria for:<br>1) the processes;<br>2) the acceptance of products and services;<br>c) determining the resources needed to achieve conformity to | Issues<br>meetings reviews |

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| | the product and service requirements;<br>d) implementing control of the processes in accordance with the criteria;<br>e) determining, maintaining and retaining documented information to the extent necessary:<br>1) to have confidence that the processes have been carried out as planned;<br>2) to demonstrate the conformity of products and services to their requirements.<br>The output of this planning shall be suitable for the organizations operations.<br>The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.<br>The organization shall ensure that outsourced processes are controlled (see 8.4). | Doc index<br>Tasks + Audit System<br>Roles + Responsibilities |
| VST Ltd<br>ISO9001:2015<br>8.2.4 | Changes to requirements for products and services<br>The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed. | |
| VST Ltd<br>ISO9001:2015<br>8.3.2 | **Design and development planning**<br>In determining the stages and controls for design and development, the organization shall consider:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties;<br>j) the documented information needed to demonstrate that design and development requirements have been met. | Design index<br>Intranstats<br><br>marketing index |
| VST Ltd<br>ISO9001:2015<br>8.3.4 | **Design and development controls**<br>The organization shall apply controls to the design and development process to ensure that:<br>a) the results to be achieved are defined;<br>b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;<br>c) verification activities are conducted to ensure that the | Design index<br>QA Intranstats |

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| | design and development outputs meet the input requirements;<br>d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;<br>e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;<br>f) documented information of these activities is retained.<br>NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization. | Procedures |
| VST Ltd<br>ISO9001:2015<br>8.3.5 | **Design and development outputs**<br>The organization shall ensure that design and development outputs:<br>a) meet the input requirements;<br>b) are adequate for the subsequent processes for the provision of products and services;<br>c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;<br>d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.<br>The organization shall retain documented information on design and development outputs. | Procedures<br>Design index<br><br>QA |
| VST Ltd<br>ISO9001:2015<br>9.1.1 | **General**<br>The organization shall determine:<br>a) what needs to be monitored and measured;<br>b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;<br>c) when the monitoring and measuring shall be performed;<br>d) when the results from monitoring and measurement shall be analysed and evaluated.<br>The organization shall evaluate the performance and the effectiveness of the quality management system.<br>The organization shall retain appropriate documented information as evidence of the results. | management +<br>other reviews<br>+ meetings<br>Procedures |
| VST Ltd<br>ISO9001:2015<br>9.2.2 | The organization shall:<br>a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;<br>b) define the audit criteria and scope for each audit;<br>c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;<br>d) ensure that the results of the audits are reported to relevant management;<br>e) take appropriate correction and corrective actions without undue delay;<br>f) retain documented information as evidence of the implementation of the audit programme and the audit results. | Audit<br>Calendar<br>citron tasks<br>VOP<br>Issues<br><br>Doc index |

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| | NOTE See ISO 19011 for guidance. | |
| Viamed Ltd ISO13485:2016 4.1.1 | **Quality management system** The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor. | Route map Issues Interststs  Doc index |
| Viamed Ltd ISO13485:2016 4.1.6 | **Quality management system** For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5). | Procedures interststs Doc index |
| Viamed Ltd ISO13485:2016 4.2 | **Documentation requirements** | |
| Viamed Ltd ISO13485:2016 4.2.1 General | **Documentation requirements** The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements. | Doc index Interststs Route map |
| Viamed Ltd ISO13485:2016 4.2.2 Quality manual | **Documentation requirements** The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; | Company structure Roles + Responsibilities |

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| | c) a description of the interaction between the processes of the quality management system.<br>The quality manual shall outline the structure of the documentation used in the quality management system. | *Vaps*<br>*Invastab* |
| Viamed Ltd<br>ISO13485:2016<br>4.2.4 Control of documents | **Documentation requirements**<br>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5.<br>A documented procedure shall define the controls needed to:<br>a) review and approve documents for adequacy prior to issue;<br>b) review, update as necessary and re-approve documents;<br>c) ensure that the current revision status of and changes to documents are identified;<br>d) ensure that relevant versions of applicable documents are available at points of use;<br>e) ensure that documents remain legible and readily identifiable;<br>f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;<br>g) prevent deterioration or loss of documents;<br>h) prevent the unintended use of obsolete documents and apply suitable identification to them.<br>The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable | *management*<br>*Review*<br>*Doc index*<br>*Intrastats* |
| Viamed Ltd<br>ISO13485:2016<br>4.2.5 Control of records | **Documentation requirements**<br>Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.<br>The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.<br>The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.<br>Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.<br>The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not | *Doc index* |

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| | less than two years from the medical device release by the organization. | |
| Viamed Ltd ISO13485:2016 5.6.1 | **General** The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained | Roles + Responsibilities Tasks + Audit System management Review |
| Viamed Ltd ISO13485:2016 7.1 | **Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971. | Design Index Issues Doc index Procedures QA infrastub |
| Viamed Ltd ISO13485:2016 7.2.2 | **Review of requirements related to product** The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: a) product requirements are defined and documented; b) contract or order requirements differing from those previously expressed are resolved; c) applicable regulatory requirements are met; d) any user training identified in accordance with 7.2.1 is available or planned to be available; e) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from | Design Index Doc index QA infrastats |

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| | the review shall be maintained (see 4.2.5).<br>When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.<br>When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. | *Procedures* |
| Viamed Ltd<br>ISO13485:2016<br>7.5.6 | **Validation of processes for production and service provision**<br>The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.<br>Validation shall demonstrate the ability of these processes to achieve planned results consistently.<br>The organization shall document procedures for validation of processes including:<br>a) defined criteria for review and approval of the processes;<br>b) equipment qualification and qualification of personnel;<br>c) use of specific methods, procedures and acceptance criteria;<br>d) as appropriate, statistical techniques with rationale for sample sizes;<br>e) requirements for records (see 4.2.5);<br>f) revalidation, including criteria for revalidation;<br>g) approval of changes to the processes.<br>The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications.<br>Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). | *VOP procedures*<br><br>*Training manager*<br><br>*Task + Audit System* |
| Viamed Ltd<br>ISO13485:2016<br>7.5.9.1 | **General**<br>The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5). | *Doc index* |
| Viamed Ltd<br>ISO13485:2016<br>8.2.4 | **Internal audit**<br>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:<br>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; | *Audit Calendar Doc index* |

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| | b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.<br><br>An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.<br><br>Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5).<br><br>The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.<br><br>NOTE Further information can be found in ISO 19011. | |
| Viamed Ltd<br>ISO13485:2016<br>8.2.5 | **Monitoring and measurement of processes**<br>The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. | Procedures Vops<br>Task + Audit<br>System<br>QA infrastats<br>Issues |
| Viamed Ltd<br>ISO13485:2016<br>8.5.2 | **Corrective action**<br>The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered.<br><br>The organization shall document a procedure to define requirements for:<br>a) reviewing nonconformities (including complaints);<br>b) determining the causes of nonconformities;<br>c) evaluating the need for action to ensure that nonconformities do not recur;<br>d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;<br>e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;<br>f) reviewing the effectiveness of corrective action taken.<br>Records of the results of any investigation and action taken shall be maintained (see 4.2.5). | Issues<br>Reviews<br>Roles + Responsibilities<br>tasks + Audits<br>Da index |

| | QUESTION: | RESPONSE: | |
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| 1 | Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory. | Nothing Outstanding | Y |
| 2 | Is there sole responsibility for company procedures and other documentation. | IT director has sole access to Intrastats system | Y |
| 3 | Verify that documentation is checked prior to formal approval and issue and authorisation is unique. | Intrastats | Y |
| 4 | Verify that all personnel have access to their relevant areas of the documentation. | Intrastats | Y |
| 5 | Verify that amendments can be requested and are controlled by Date issue. are updated Electronically and old copies Archived. | Intrastats | Y |
| 6 | Check that the C.E. files are maintained by sole responsibility. | MD | Y |
| 7 | Check that obsolete data in the files is Archived | Intrastats also Archives store | Y |
| 8 | Are manufacturers data sheets supplied the latest issue. Supplier Review. As and when informed by supplier | Intrastats | Y |
| 9 | Verify that checks are made to ascertain the latest issue data sheets are supplied after design change / modification (from suppliers). | Intrastats | Y |
| 10 | Are Intrastat documents regularly backed-up and secure offsite Task ID (452) | Intrastats – Roles and Responsibilities. Task ID (452) # 196798 | Y |
| 11 | Check that the document register is complete and adequate. | Intrastats | Y |
| 12 | Check that documents are filed where they say they are and the responsibility is true. | Intrastats on workstation | Y |
| 13 | Verify that records are easily retrievable for information and analysis. | Intrastats on workstation | Y |
| 14 | Are printed copies of production procedures the latest issue status. | No printed copies | N/A |
| 15 | Is the procedure for ensuring only the latest issue of drawings and documentation available working correctly Check 6 items in the Index. Task ID (371) | Intrastats. Task ID (371) # 194821 within terms | Y |
| 16 | Are quality records properly filed and easily retrievable. | Intrastats | Y |
| 17 | Is the Company procedures Manual the latest version. | Intrastats | Y |
| 18 | Has the organisation chart changed. VST 23 April 19 Viaм 20 Sept 18 | | NO |
| 19 | Has the responsibility descriptions changed. | Intrastats – Roles and Responsibilities | N |
| 20 | Stock linked document – have documents been linked to stock correctly. ISO – Document Index Admin – Complete Amendment Log – look down the list for stock related documents, then see if the stock link is present. The list shows the last 3 months. | Doc Id 43431 ✓ Doc Id 43429 ✓ | Y |
| 21 | Duplicate Documents – Task ID (370) – ISO – Documentation Index Admin – find duplicate files. This should be empty. Make a note of the number and dates. | # 194132 ✓ | Y |

Sub Processes Linked to Audit 10

Review the below processes tasks and audits and ensure they are completed in a timely manner.

**List Processes Per Title**

### Managing Director

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
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| PROCESSID **5877** To review the numbers of various departments. Showing increasing / reducing staff requirements *# 195987 in terms # 197063* | 114 Managing Director | 561 Company Secretary | Freq 3 Risk 1 Overall 3 | Task 1M Audit 12M | |

### Product Controller

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|
| PROCESSID **7032** | | | Freq Risk Overall | | |
| PROCESSID **7863** To confirm the current repairs codes for various products in the system are up to date and available to office members of staff. *#156076* *#156077* | 772 Director 3 (Steve) | 773 Managing Director | Freq 1 Risk 1 Overall 1 | Task 12M Audit 24M | |

### Documentation And Records Controller

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
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| PROCESSID **41** Allocation of overall responsibility | | | Freq Risk Overall | | |
| PROCESSID **59** Check the Document Index for any out of date documents, *In terms #194821 #195700* | 371 Managing Director | 372 Company Secretary | Freq 3 Risk 1 Overall 3 | Task 1M Audit 6M | |
| PROCESSID **5851** Removal of Duplicate documents *# 197138 # 194955* | 370 Managing Director | 369 Company Secretary | Freq 3 Risk 1 Overall 3 | Task 1M Audit 6M | |
| PROCESSID **5852** *# 195991* | | | Freq Risk Overall | | |
| PROCESSID **5940** Generate the Thumbs nails for the document Index | 155 Managing Director | | Freq 3 Risk 1 Overall 3 | Task 1M | |

### IT Controller

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| PROCESSID **44**<br>Encrypt data sent back and forth to Intrastats so it can be used off site<br># 195559 ✓ | 412<br>Managing Director | | Freq 1<br>Risk 1<br>Overall 1 | Task 12M | |
| PROCESSID **52**<br>Keeps a month or so backup emails<br>#196784 | 368<br>Managing Director<br>#189940 ✓ | 417<br>Company Secretary | Freq 4<br>Risk 1<br>Overall 4 | Task 2W<br>Audit 3M | |
| PROCESSID **53**<br>Maintain the Online Email boxes currently Google and Goldmine | | 902<br>Accounts Processes<br># 197494 ✓ | Freq 1<br>Risk 1<br>Overall 1 | Audit 1W | |
| PROCESSID **5939**<br>Email routing to End Users | | | Freq 1<br>Risk 1<br>Overall 1 | | |
| PROCESSID **7124**<br>No Process, Responsibilitys only | | | Freq<br>Risk<br>Overall | | |
| PROCESSID **7125**<br>To fix Urgent Problems with Intrastats | | | Freq 1<br>Risk 1<br>Overall 1 | | |
| PROCESSID **7126**<br>Fix general errors in intrastats such as Spelling errors or columns not lining up<br>#196012 | 458<br>Managing Director<br>in terms | | Freq 3<br>Risk 1<br>Overall 3 | Task 1M | |
| PROCESSID **7127** | | | Freq<br>Risk<br>Overall | | |
| PROCESSID **7128** | | | Freq<br>Risk<br>Overall | | |
| PROCESSID **7129**<br>Update the online Cross reference guides with latest intrastats data.<br>#196346 | 462 ✓<br>Managing Director | 457<br>Director 3 (Steve)<br>#196667 | Freq 3<br>Risk 1<br>Overall 3<br>— | Task 1M<br>Audit 3M | |
| PROCESSID **7130**<br>To Review the L Drive Library is in sync with Intrastats Documentation<br>#195737 ✓ | 791<br>Managing Director | | Freq 3<br>Risk 1<br>Overall 3 | Task 1M | |
| PROCESSID **7131**<br>Maintain Syncronization Between Accounts package Opera and Intrastats | | | Freq 1<br>Risk 3<br>Overall 3 | | |
| PROCESSID **7133** | | | Freq<br>Risk<br>Overall | | |
| PROCESSID **7672**<br>To take a copy of the important data off-site<br>#198305<br>in terms | 452 | 453<br>Company Secretary<br>#195392 ✓ | Freq 5<br>Risk 1<br>Overall 5 | Task 3D<br>Audit 1M | |

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|
| PROCESSID **7700**<br>Maintain Domains for websites<br><br>#197902 interns | 510 | | Freq 3<br>Risk 1<br>Overall 3 | Task<br>1M | |
| PROCESSID **7739**<br>Intrastat Changes updates.<br>Logging system to enable roll<br>back should anything break<br><br>#197767 ✓ | 562<br>Managing<br>Director | | Freq 4<br>Risk 1<br>Overall 4 | Task<br>1W | |

## ISO Controller

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|
| PROCESSID **5890**<br>Ensure the online available copies<br>of our ISO standards are upto date<br><br>#196482 ✓  #189035 ✓ | 463<br>Managing<br>Director | 464<br>Marketing<br>Processes | Freq 3<br>Risk 1<br>Overall 3 | Task<br>1M<br>Audit<br>6M | |

## Office Team Leader

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|
| PROCESSID **6938**<br>Updating the data base with new<br>and updated customer<br>information, treating it with<br>respect and keeping it secure. | | | Freq 1<br>Risk 1<br>Overall 1 | | |
| PROCESSID **6940** | | | Freq<br>Risk<br>Overall | | |
| PROCESSID **7090** | | | Freq<br>Risk<br>Overall | | |

## Accounts Processes

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|
| PROCESSID **7922**<br>To back up Journals and other<br>docs that have been saved in<br>Emilys users folder.<br><br>Journal are checked monthly so<br>they need to be in the Journals<br>folder to be able to be checked. | 934 | | Freq 1<br>Risk 2<br>Overall 2 | | |

## Audits

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|
| PROCESSID **7722**<br>To carry out Audit 10<br>Documentation Control Viamed | | 27 #186610<br>Company<br>Secretary | Freq 1<br>Risk 2<br>Overall 2 | Audit<br>12M | |
| PROCESSID **7770**<br>To carry out Audit 10<br>Documentation Control VST | | 183 #186613<br>Company<br>Secretary | Freq 1<br>Risk 2<br>Overall 2 | Audit<br>12M | |

## Office Processes

| Process Scope | Roll Task | Roll Audit | Risk | Action | Notes / Issues |
|---|---|---|---|---|---|
| PROCESSID **6** <br> Updating Contact Management System | | | Freq 1 <br> Risk 1 <br> Overall 1 | | |
| PROCESSID **9** <br> Distribute recieved faxs | 824 | | Freq 1 <br> Risk 1 <br> Overall 1 | | |
| PROCESSID **10** <br> Distribute Emails <br> #197453 | /366 <br> Managing Director | Freq 3 <br> Risk 1 <br> Overall 3 | Audit <br> 1M | |
| PROCESSID **11** <br> Distibuting incoming post to correct person | 599 <br> Office# 198326 <br> Processes | | Freq 3 <br> Risk 1 <br> Overall 3 | Task <br> 1D | |
| PROCESSID **12** <br> To receive, collate and store the sales and technical information received in to the companies | | | Freq 1 <br> Risk 1 <br> Overall 1 | | |
| PROCESSID **15** <br> Paperwork to be filed in the correct order <br> #198299 | 567 <br> Office <br> Processes | 16 <br> Company <br> Secretary <br> #170003 | Freq 4 <br> Risk 1 <br> Overall 4 | Task <br> 1D <br> Audit <br> 12M | |
| PROCESSID **16** | | | Freq <br> Risk <br> Overall | | |
| PROCESSID **5901** <br> To link new calls to Contacts in the CRM <br> #197879 | 404 <br> Office <br> Processes | 405 <br> Company <br> Secretary <br> #197880 | Freq 4 <br> Risk 1 <br> Overall 4 | Task <br> 1W <br> Audit <br> 1M | |
| PROCESSID **7693** <br> Collect the filing form the warehouse <br> #197758 | 506 <br> Office <br> Processes | 507 <br> #195124 | Freq 4 <br> Risk 1 <br> Overall 4 | Task <br> 1W <br> Audit <br> 1M | |
| PROCESSID **7699** <br> Shredding of sensitive information <br> #197759 | 508 <br> Office <br> Processes | 509 <br> Office <br> Processes <br> #198315 | Freq 4 <br> Risk 1 <br> Overall 4 | Task <br> 1W <br> Audit <br> 1M | |
| PROCESSID **7705** <br> Checking if a customer has uploaded an order directly to our website <br> #198316 | 517 <br> Office <br> Processes | 518 <br> Office <br> Processes <br> #198317 | Freq 5 <br> Risk 1 <br> Overall 5 | Task <br> 1D <br> Audit <br> 1W | |
| PROCESSID **7711** <br> Download the most recent bank statement from the bank website <br> #198319 | 526 <br> Office <br> Processes | 527 <br> Company <br> Secretary <br> #197763 | Freq 5 <br> Risk 1 <br> Overall 5 | Task <br> 1D <br> Audit <br> 1W | |