Internal Audit Check list			
Internal Process Verification			
Created:	17 May 1995	**Audit No 10b**	
Revised:	28 October 2017		Page 1 of 1
Audit Date		Auditor	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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 quality management system and their application throughout the organization, and shall: a) determine the inputs required and the outputs expected from these processes; b) determine the sequence and interaction of these processes; 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; d) determine the resources needed for these processes and ensure their availability; e) assign the responsibilities and authorities for these processes; f) address the risks and opportunities as determined in accordance with the requirements of 6.1; g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; h) improve the processes and the quality management system	
VST Ltd ISO9001:2015 5.2.1	**Establishing the quality policy** Top management shall establish, implement and maintain a quality policy that: a) is appropriate to the purpose and context of the organization and supports its strategic direction; b) provides a framework for setting quality objectives; c) includes a commitment to satisfy applicable requirements; d) includes a commitment to continual improvement of the quality management system.	
VST Ltd ISO9001:2015 5.3	**Organizational roles, responsibilities and authorities** Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management shall assign the responsibility and authority	

	for: a) ensuring that the quality management system conforms to the requirements of this International Standard; b) ensuring that the processes are delivering their intended outputs; c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management; d) ensuring the promotion of customer focus throughout the organization; e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	
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	
VST Ltd ISO9001:2015 7.1.2	**People** The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.	
VST Ltd ISO9001:2015 7.5.1	**General** 7.5.1 General The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management system can differ from one organization to another due to: — the size of organization and its type of activities, processes, products and services; — the complexity of processes and their interactions; — the competence of persons.	
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ISO9001:2015 7.5.3.1	Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed; b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).	
VST Ltd ISO9001:2015 7.5.3.2	For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use; b) storage and preservation, including preservation of legibility; c) control of changes (e.g. version control); d) retention and disposition. 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. Documented information retained as evidence of conformity shall be protected from unintended alterations. 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.	
VST Ltd ISO9001:2015 8.3.6	**Design and development changes** The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts.	
VST Ltd ISO9001:2015 8.5.5	**Post-delivery activities** The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback.	

	NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	
VST Ltd ISO9001:2015 8.7.2	The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity.	
VST Ltd ISO9001:2015 9.2.1	The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained.	
VST Ltd ISO9001:2015 9.3.3	**Management review outputs** The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement; b) any need for changes to the quality management system; c) resource needs. The organization shall retain documented information as evidence of the results of management reviews.	
Viamed Ltd ISO13485:2016 4.1.2	**Quality management system** The organization shall: a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization; b) apply a risk based approach to the control of the appropriate processes needed for the quality management system; c) determine the sequence and interaction of these processes.	
Viamed Ltd ISO13485:2016 4.1.3	**Quality management system** For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these	

	processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).	
Viamed Ltd ISO13485:2016 4.1.4	**Quality management system** For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system c) controlled in accordance with the requirements of this International Standard and applicable regulatory 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.	
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; c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	
Viamed Ltd ISO13485:2016 5.3	**Quality policy** Top management shall ensure that the quality policy: a) is applicable to the purpose of the organization;	

	b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; c) provides a framework for establishing and reviewing quality objectives; d) is communicated and understood within the organization; e) is reviewed for continuing suitability.	
Viamed Ltd ISO13485:2016 5.4.2	**Quality management system planning** Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	
Viamed Ltd ISO13485:2016 6.1	**Provision of resources** The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness; b) meet applicable regulatory and customer requirements.	
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 the review shall be maintained (see 4.2.5). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. 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.	
Viamed Ltd ISO13485:2016 7.3.1	**General** The organization shall document procedures for design and development	
Viamed Ltd ISO13485:2016	**Design and development planning** The organization shall plan and control the design and	

7.3.2	development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development; e) the methods to ensure traceability of design and development outputs to design and development inputs; f) the resources needed including necessary competence of personnel	
Viamed Ltd ISO13485:2016 7.3.3	**Design and development inputs** Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include: a) functional, performance, usability and safety requirements, according to the intended use; b) applicable regulatory requirements and standards; c) applicable output(s) of risk management; d) as appropriate, information derived from previous similar designs; e) other requirements essential for design and development of the product and processes. These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other. NOTE Further information can be found in IEC 62366–1.	
Viamed Ltd ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; 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. 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. 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). 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. NOTE Further information can be found in ISO 19011.	
Viamed Ltd ISO13485:2016 8.3.4	**Rework** The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016 8.5.2	**Corrective action** 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. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; 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; f) reviewing the effectiveness of corrective action taken Records of the results of any investigation and action taken shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016	**Preventive action** The organization shall determine action to eliminate the causes	

8.5.3	of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; e) reviewing the effectiveness of the preventive action taken, as appropriate. Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).	

	QUESTION:	**RESPONSE**	**Y/N**
1	Is the Quality Statement Policy and Objectives reviewed annually. ISO – Document Index Task ID (300). Search Issues and review.		
2	Is the process manual up to date. ISO – Document Index Task ID (548). Search Issues and review.		
3	Is documentation checked prior to formal approval and issue.		
4	Check that there is a system in operation for the request for amendments.		
5	Verify that amendments are updated electronically and old copies archived.		
6	Are sales orientated records filed and archived correctly in the ORD files, in the office and archiving.		
7	Has organisation Chart changed.		
8	Has personnel responsibility descriptions changed.		
9	Check that the CE files are maintained by sole responsibility.		
10	Check that the Notified body is informed of major changes to Documentation.		
11	Check that electronic documents are regularly backed up and secure off site. ISO – Document Index Task ID (452). Search Issues and review.		

Sub Processes Linked to Audit 10b

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

Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7837** To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks	743 Managing Director	784 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7845** Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.	745 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7846** To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13	746 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7848** To Review the Scope of the ISO 9001 / ISO 13485 Standards	749 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7871** To review the Exclusions / boundaries to ISO 13485:2016 for Viamed	790 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	

IT Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7701**	511		Freq 3	Task	

Amazon Web Services, is an online service, which basically simply provides a Linux PC out on the Web. Viamed uses this, for Web development of Websites: It hosts a working backup of many websites. Viamed / vst / vandagraph etc..	Managing Director		Risk 1 Overall 3	1M
PROCESSID **7755** To Send Invoice for online services to Helen	597 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M
PROCESSID **7832** Backup of all Sent Emails sent to External Address for Verification	731 Managing Director		Freq 4 Risk 1 Overall 4	Task 2W
PROCESSID **7850** Test the Goods out process disabling picking of items not relating to an order	752 Goods Out	753 Goods In	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M
PROCESSID **7851** To test intrastats does not allow picking of unprocessed products to live customer orders	754 Goods Out	755 Goods In	Freq 3 Risk 4 Overall 12	Task 1M Audit 3M
PROCESSID **7852** To attempt to Scan a product that has gone past its expire date.	756 Goods Out	757 Goods In	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M
PROCESSID **7853** Warehouse shelfs can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders. Test that Order picking cannot pick unsellable stock locations to an Order	759 Goods Out	760 Goods In	Freq 3 Risk 3 Overall 9	Task 1M Audit 3M
PROCESSID **7854**	761	762	Freq 2	Task

Software Validation of the production lists. By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated	Goods In	Managing Director	Risk 2 Overall 4	3M Audit 6M
PROCESSID **7855** Software Validation - Production Lists Review the current active production lists inintrastats to the actual in progress production lists	761 Goods In	762 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
PROCESSID **7856** To check order picking cannot pick against an unchecked order	764 Office Processes	765 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 12M
PROCESSID **7857** To confirm Software Validation Stock Tracking Check, is functioning as expected	763 Goods In		Freq 2 Risk 1 Overall 2	Task 6M
PROCESSID **7858** Test the QA System that Staff not trained for QA are unable to QA a Product.	766 Office Processes		Freq 3 Risk 3 Overall 9	Task 1M
PROCESSID **7861** Software Validating Of Training Documents via Forced Required Reading	768 Managing Director		Freq 1 Risk 2 Overall 2	Task 12M
PROCESSID **7865** Software Validiation of the system: To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit.	779 Managing Director	781 Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID **7870** Scope to check the automatic system of tagging product non conformance and other	789 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M

issues to the post market surveillance review report.

ISO Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **6866** Review the Internal Process and Verification`s are suitable for the current standards	55 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7827** To review the Quality policy and check it is still valid and upto date.	301 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7828** To review the Quality policy and check it is still valid and upto date.	723 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7723** To carry out Audit 10b Process Verification Viamed		3 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7771** To carry out Audit 10b Process Verification VST		177 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	