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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 7.5.2	**Creating and updating** 7.5.2 Creating and updating When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy.	
VST Ltd ISO9001:2015 7.5.3	**Control of documented information**	
VST Ltd ISO9001:2015 8.1	**Operational planning and control** 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: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining, maintaining and retaining documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) to demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the organizations operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as	

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	necessary. The organization shall ensure that outsourced processes are controlled (see 8.4).	
Viamed Ltd ISO13485:2016 4.2.4 Control of documents	**Documentation requirements** 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. A documented procedure shall define the controls needed to: a) review and approve documents for adequacy prior to issue; b) review, update as necessary and re-approve documents; c) ensure that the current revision status of and changes to documents are identified; d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; 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; g) prevent deterioration or loss of documents; h) prevent the unintended use of obsolete documents and apply suitable identification to them. 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	
Viamed Ltd ISO13485:2016 5.6.2	**General**	

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Review input	The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.	
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.	
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 7.3.4	**Design and development outputs** Design and development outputs shall: a) meet the input requirements for design and development; b) provide appropriate information for purchasing, production and service provision; c) contain or reference product acceptance criteria; d) specify the characteristics of the product that are essential for its safe and proper use. The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release. Records of the design and development outputs shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016 7.4.2	**Purchasing information** Purchasing information shall describe or reference the product to be purchased, including as appropriate:	

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	a) product specifications; b) requirements for product acceptance, procedures, processes and equipment; c) requirements for qualification of supplier personnel; d) quality management system requirements. The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).	
Viamed Ltd ISO13485:2016 7.5.4	**Servicing activities** If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016 7.6	**Control of monitoring and measuring equipment** The organization shall determine the monitoring and measurement to be undertaken and the	

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	monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5); b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5); c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.5). The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.	

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	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. 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). NOTE Further information can be found in ISO 10012.	
Viamed Ltd ISO13485:2016 8.1	**General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to: a) demonstrate conformity of product; b) ensure conformity of the quality management system; c) maintain the effectiveness of the quality management system. This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.	
Viamed Ltd ISO13485:2016 8.2.1	**Feedback** As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented. The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. If applicable regulatory requirements require the	

	organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.	
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	

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	19011.	
Viamed Ltd ISO13485:2016 8.2.5	**Monitoring and measurement of processes** 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.	
Viamed Ltd ISO13485:2016 8.3.1	**General** The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5)	
Viamed Ltd ISO13485:2016 8.4	**Analysis of data** The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:	

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	a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016 8.5.1	**General** The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.	

	QUESTION:	**RESPONSE:**	**Y/ N**
1	Check that the information register is complete and correct Replaced with Intrastats Document Index	Document index	N/A
2	Verify that meetings take place to the required periodicity. Intrastats – Meeting – Host Meeting – Review Page Done Oct 17 not	Issue Sent #126623 Board meeting. needed	Y Y
3	Check that the correct personnel are involved in these meetings.	Roles and Responsibilities	Y

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4	Verify that minutes are filed accordingly. Intrastats – Meeting – Host Meeting – check History and then click the Meeting Title.		Y
5	Do the meetings produce subsequent personnel plans of action.	Issues where needed	Y
6	Are these actions followed up in a timely manner? Task Id 114 - Check anomalies in Data Issues need to add - All Issues statshcs - Chase any long standing Issues #126628		
7	Check that relevant information and data is collated for further presentation. Intrastats		Y

Sub Processes Linked to Audit
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 **26** Overview of the Company using various data Reporting Screens	114 125473 ✓ Managing Director		Freq 3 Risk 1 Overall	Task 1M	
PROCESSID **27** To review and Close all automatic rolling Issues. Including all rolling tasks and audits	290 125738 ✓ Managing Director	775 118353 ✓ Company Secretary	Freq 4 Risk 1 Overall 4	Task 1W Audit 6M	
PROCESSID **5877** To review the numbers of various departments. Showing increasing / reducing staff requirements	125473 114 ✓ Managing Director	105301 561 ✓ Company Secretary	Freq 3 Risk 0 Overall	Task 1M Audit 12M	
PROCESSID **6931** Review the Customer Complaints Heading	125564 728 ✓ Managing Director	119612 774 ✓ Company Secretary	Freq 4 Risk 1 Overall	Task 1W Audit	

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			4	6M
PROCESSID **7070** To discuss any problems, to assess work load and staffing. To review issues.	83 ✓ 125071 Managing Director		Freq 2 Risk 1 Overall 2	Task 3M
PROCESSID **7713** Ensure All tasks allocated to active Members of staff,	548 ✓ 124331 Managing Director		Freq 3 Risk 2 Overall 6	Task 1M
PROCESSID **7830** To review the Quantities of Failed product per Stock reference Passing through the Q.A. system	727 125188 ✓ Goods In	729 125130 ✓ Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M
PROCESSID **7837** To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks	743 104284 ✓ Managing Director	784 107014 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID **7838** Review Customer Feedback Negative	739 ✓ 124470 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M
PROCESSID **7839** To Review Viamed Customer Complaints	737 ✓ 124468 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M
PROCESSID **7840** To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	740 ✓ 124471 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M
PROCESSID **7841** To review Customer Complaints see if Non Conformance need to be raised	738 ✓ 124469 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M
PROCESSID **7842**	741 ✓ 124472		Freq 3	Task 1M

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To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	Managing Director		Risk 1 Overall 3	
PROCESSID **7843** To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise	742 124673 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M
PROCESSID **7849** Review the Customer Returns and Review Product Failures New Codes	750 125862 ✓ Managing Director	751 125131 ✗ 1st Aug still in terms Director 3 (Steve)	Freq 4 Risk 3 Overall 12	Task 1W Audit 3M

ISO Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **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.	50 124008 Managing Director	14 119282 Company Secretary	Freq 3 Risk 4 Overall 12	Task 2M Audit 12M	Waiting on Derek to review

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7733** To carry out Audit 23 Analysis Of Data Viamed		43 123911 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	this Audit
PROCESSID **7781** To carry out Audit 23 Analysis Of Data VST		123914 this Audit 185 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

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