

Internal Audit Check List

Verneel VST

ANALYSIS of DATA

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Revised:	12 June 2017		
Audit Date	24-7-19	Auditor Helen Combs	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 7.5.2	<p>Creating and updating</p> <p>7.5.2 Creating and updating</p> <p>When creating and updating documented information, the organization shall ensure appropriate:</p> <ol style="list-style-type: none"> identification and description (e.g. a title, date, author, or reference number); format (e.g. language, software version, graphics) and media (e.g. paper, electronic); review and approval for suitability and adequacy. 	Doc index Marketing info
VST Ltd ISO9001:2015 7.5.3	<p>Control of documented information</p> <p>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:</p> <ol style="list-style-type: none"> determining the requirements for the products and services; establishing criteria for: <ol style="list-style-type: none"> the processes; the acceptance of products and services; determining the resources needed to achieve conformity to the product and service requirements; implementing control of the processes in accordance with the criteria; determining, maintaining and retaining documented information to the extent necessary: <ol style="list-style-type: none"> to have confidence that the processes have been carried out as planned; to demonstrate the conformity of products and services to their 	Marketing info Doc index Review Policy tasks + Analysis

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<p>Viamed Ltd ISO13485:2016</p> <p>4.2.4 Control of documents</p> <p>The organization shall ensure that outsourced processes are controlled (see 8.4).</p>	<p>Documentation requirements</p> <p>Records are a special type of document and shall be controlled according to the requirements given in 4.2.5.</p> <p>A documented procedure shall define the controls needed to:</p> <p>a) review and approve documents for adequacy prior to issue;</p> <p>b) review, update as necessary and re-approve documents;</p> <p>c) ensure that the current revision status of and changes to documents are identified;</p> <p>d) ensure that relevant versions of applicable documents are available at points of use;</p> <p>e) ensure that documents remain legible and readily identifiable;</p> <p>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;</p> <p>g) prevent deterioration or loss of documents;</p> <p>h) prevent the unintended use of obsolete documents and apply suitable identification to them.</p> <p>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</p>	<p>Q & Repairs</p> <p>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 necessary.</p> <p>The organization shall ensure that outsourced processes are controlled (see 8.4).</p> <p>Supplier Review</p> <p><i>all documents</i></p> <p><i>Review & updates</i></p>

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<p>Viamed Ltd ISO13485:2016</p> <p>5.6.2 Review input</p>	<p>General</p> <p>The input to management review shall include, but is not limited to, information arising from:</p> <ul style="list-style-type: none"> 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. 	<p>base its decisions.</p> <p>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</p> <p><i>All documents retained.</i></p>
<p>Viamed Ltd ISO13485:2016</p> <p>7.1</p>	<p>Planning of product realization</p> <p>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.</p> <p>The organization shall document one or more processes for risk management</p>	<p><i>Design tech files in markets.</i></p>

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<p>Viamed Ltd ISO13485:2016</p> <p>7.3.3</p> <p>Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include:</p> <p>a) functional, performance, usability and safety requirements, according to the intended use;</p> <p>b) applicable regulatory requirements and standards;</p> <p>c) applicable output(s) of risk management;</p> <p>d) as appropriate, information derived from previous similar designs;</p> <p>e) other requirements essential for design and development of the product and processes.</p> <p>These inputs shall be reviewed for adequacy and approved.</p>	<p>in product realization.</p> <p>Records of risk management activities shall be maintained (see 4.2.5).</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <p>a) quality objectives and requirements for the product;</p> <p>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;</p> <p>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;</p> <p>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5).</p> <p>The output of this planning shall be documented in a form suitable for the organization's method of operations.</p> <p>NOTE Further information can be found in ISO 14971.</p>	<p><i>Design files & tech files</i></p> <p><i>Instructions, procedures, QA</i></p> <p><i>Doc index</i></p>
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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.

Design and development outputs
 Design and development outputs shall:

- meet the input requirements for design and development;
- provide appropriate information for purchasing, production and service provision;
- contain or reference product acceptance criteria;
- 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).

Purchasing information
 Purchasing information shall describe or reference the product to be purchased, including as appropriate:

- product specifications;
- requirements for product acceptance, procedures, processes and equipment;
- requirements for qualification of supplier personnel;
- 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

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Viamed Ltd ISO13485:2016	7.5.4	<p>to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.</p> <p>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).</p>	<p>Servicing activities</p> <p>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.</p> <p>The organization shall analyse records of servicing activities carried out by the organization or its supplier:</p> <ul style="list-style-type: none"> a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. <p>Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).</p>
Viamed Ltd ISO13485:2016	7.6	<p>Control of monitoring and measuring equipment</p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.</p> <p>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.</p> <p>As necessary to ensure valid results, measuring equipment shall:</p> <ul style="list-style-type: none"> 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); 	<p>Complaints file + Procedures Workshops.</p> <p>Issues</p> <p>Calibration index QA Records Procedures Workshops</p>

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Viamed Ltd ISO13485:2016 8.1	General	<p>b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5);</p> <p>c) have identification in order to determine its calibration status;</p> <p>d) be safeguarded from adjustments that would invalidate the measurement result;</p> <p>e) be protected from damage and deterioration during handling, maintenance and storage.</p> <p>The organization shall perform calibration or verification in accordance with documented procedures.</p> <p>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.</p> <p>Records of the results of calibration and verification shall be maintained (see 4.2.5).</p> <p>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. 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.</p> <p>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).</p> <p>NOTE Further information can be found in ISO 10012.</p>	<i>Regular Issues for test /calibration procedures</i>

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Viamed Ltd ISO13485:2016	<p>analysis and improvement processes needed to:</p> <p>a) demonstrate conformity of product;</p> <p>b) ensure conformity of the quality management system;</p> <p>c) maintain the effectiveness of the quality management system.</p> <p>This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.</p>	QA + Doc index	
8.2.1	<p>Feedback</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>If applicable regulatory requirements require the organization to gain specific experience from post production activities, the review of this experience shall form part of the feedback process.</p>	Issues + Workshops	
Viamed Ltd ISO13485:2016	<p>Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p>	<i>Issues Mrs Vops + Cops Analysts Reviewed</i>	
	The organization shall document a procedure to describe the responsibilities		

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<p>and requirements for planning and conducting audits and recording and reporting audit results.</p> <p>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.</p> <p>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).</p> <p>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.</p> <p>NOTE Further information can be found in ISO 19011.</p>			
Viamed Ltd ISO13485:2016	Monitoring and measurement of processes	QA Procellmer	
8.2.5	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.	Uncheck	
Viamed Ltd ISO13485:2016	General	Bar Circle marking.	
8.3.1	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,		

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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.
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QUESTION:	RESPONSE:	Y/N
1 Check that the information register is complete and correct.		Y <i>Intrastats Controlled</i>
2 Verify that meetings take place to the required periodicity.		Y <i>VST Board Meeting overdue</i>
3 Check that the correct personnel are involved in these meetings.	Roles and Responsibilities	Y
4 Verify that minutes are filed accordingly.		<i>Automatic</i>
Intrastats – Meeting – Host Meeting – check History and then click the Meeting Title.		Y

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5	Do the meetings produce subsequent personnel plans of action.	Y follow up issues added at time of meeting
6	Are these actions followed up in a timely manner? (746) <i>Yearly management review</i>	Act on Issues # 135684 time change due to Audit calendar changes. Document to cover this.
7	Check that relevant information and data is collated for further presentation. Intrastats	See above

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	Brief Description	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Ove rall	Action
26 - <i>History/Details</i>	Company Resources	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, data Reporting Screens Analysis Data	114 none - this is a subjective review by the Managing Director	148866 Managing Director	✓	3	1	3	Task 1M
27 - <i>History/Details</i>	Management To review and close all	16995 VM3COP27.17 Reviews And Complete Auto_calender	290	150211 Review the Management Review Rolling Issues page, Managing Company	✓	775	4	1	4 Task 1W

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automatic rolling Issues. Quality Issues	Director	Secretary	Audit
Including all rolling Audits			6M
tasks and audits			
27178 VOP 13 Process			
Monitoring, System			
Reviews, Audits,			
Management Review,			
Analysis Data			
27178 VOP 13 Process			
Monitoring, System			
Reviews, Audits,			
Data			
Management Review,			
Analysis Data			
22588 VM3COP02.02 VST			
Company Responsibilitys			
organisation chart structure			
27474 VM3COP02.02			
Viamed Company			
Responsibilitys organisation			
chart structure			
6931 - <i>History/Details</i>			
Review the Customer Complaints Heading	Customer Complaints	Customer Complaints	ISO - ISO Review - Non Conformance / Customer Complaints Review
	Vigilance and Notifications	Vigilance and Notifications	Are all those listed reviewed.
	Viamed Ltd	Viamed Ltd	
24129 VOP 19 FeedBack			Do they have ticks where necessary, tasks, issues and completion notes added.
Customer Complaints			
Vigilance and Notifications			
VST Ltd			Check the previous months.

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7070 - History/Details	Management Review	27178 VOP 13 Process	83	2 1 2 Task 3M
To discuss any problems, to assess work load and staffing.	To review issues.	Monitoring, System Reviews, Audits, Management Review, Analysis Data	Managing Director	
		24125 VOP 19 FeedBack	none - this is a subjective review by the Management of the current state of staffing / workload etc.	
		Customer Complaints		
		Vigilance and Notifications		
		VST Ltd		
7713 - History/Details	Review Roles And Responsibility and Staffing Issues, Training, Roles and Tasks	No Job Clashes in the list (Aside from Software Validation Conflicting Audits)	548	3 2 6 Task 1M
Ensure All tasks allocated to active Members of staff,	ys	No Yellow Employees in the list (aside from Auditor)	Managing Director	
		No Areas with High outstanding Issues	149966 ✓	
7830 - History/Details	Review Q.A. Failures Report	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	727 Goods In	729 3 1 3 Task 1M
To review the Quantities of Failed product per Stock reference Passing through the Q.A. system		Quantities of Failed product per Stock reference Passing through the Q.A. system	Managing Director	Audit 3M

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7837 - History/Details	Review To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks	Review External Parties Influencing The QMS VST / Viamed Viamed	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks 27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data
			743 Managing Director
			784 Company Secretary
			1 1 1 Task 12M Audit 12M
7838 - History/Details	Review Customer Feedback Negative	Review VIAMED Feedback - Customer Feedback Negative	Go to the meeting heading Customer Feedback Negative and review the last 3 months, or since last review
			739 Managing Director
			3 1 3 Task 1M
7839 - History/Details	To Review Viamed Customer Complaints	Review VIAMED Feedback - Customer Complaints	24125 VOP 19 FeedBack Go to the meeting heading Customer Complaints and review the last 3 months, or since last review
			737 Managing Director
			1 1 3 Task 1M
7840 - History/Details	To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	Review VST Feedback - Customer Feedback Viamed Ltd Negative	149959 149962 Go to the meeting heading Customer Feedback Negative and review the last 3 months, or since last review
			740 Managing Director
			3 1 3 Task 1M

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7841 - <i>History/Details</i>	Review VST	24125 VOP 19 FeedBack	Go to the meeting heading Customer Complaints	738	14963
To review Customer Complaints	Feedback - Customer Complaints	Vigilance and Notifications	Customer Complaints and review the last 3 months, or since last review	Managing	3 1 3 Task 1M
see if Non Conformance need to be raised	Viamed Ltd			Director	
7842 - <i>History/Details</i>	Review VIAMED	24125 VOP 19 FeedBack	Go to the meeting heading Customer Complaints	741	14963
To review Negative feedback form Products	Product Product	Vigilance and Notifications	Product Feedback Negative and review the last 3 months, or since last review	Managing	3 1 3 Task 1M
see if Non Conformance or customer Complaints	Feedback Negative	Viamed Ltd		Director	
need to be raised					
7843 - <i>History/Details</i>	Review VST	24125 VOP 19 FeedBack	Go to the meeting heading Customer Complaints	742	14964
To review Negative feedback form Products	Product Feedback	Vigilance and Notifications	Product Feedback Negative and review the last 3 months, or since last review	Managing	3 1 3 Task 1M
see if Non Conformance or customer Complaints	Negative	Viamed Ltd		Director	
need to be raise					
7849 - <i>History/Details</i>	Review	24121 VOP 10 Non Conformance, Corrective and Preventive Actions	150359 131321 + + #150376		
Review the Customer Returns and Review Product Failures	Product Failures New	Codes			
Codes					

ISO Controller

Process Scope	Responsibility/Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Ove rall	Action
7071 - <i>History/Details</i>	Post Market	27178 VOP 13 Process	50 149566	143623	14	3	4	12 Task

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The process by which review 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.

Monitoring, System
Reviews, Audits,
Management Review,
Analysis Data

<div The process by which review 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.

Audits

Brief Description	Responsibility/Procedure/ Measurable Objective	Task	Audit	Freq	Risk	Overall
7733 - <i>History/Details</i>	Audit 23	27178 VOP 13 Process	Audit 23	2	Audit	Audit 23
To carry out Audit 23	Analysis Of Data	Data Viamed	Monitoring, System	Reviews, Audits,	Reviews, Audits	Reviews, Audits
Analysis Of Data	Data Viamed	Management Review,	Management Review,	Management Review,	Management Review,	Management Review,
7781 - <i>History/Details</i>	Audit 23	27178 VOP 13 Process	Audit 23	2	Audit	Audit 23
To carry out Audit 23	Analysis Of Data VST	Data VST	Monitoring, System	Reviews, Audits,	Reviews, Audits	Reviews, Audits
Analysis Of Data	Data VST	Management Review,	Management Review,	Management Review,	Management Review,	Management Review,
185	1 2	Audit	Audit	2	Audit	Audit
Company	Secretary	Secretary	Secretary	2	Audit	Audit
Secretary	Secretary	Secretary	Secretary	2	Audit	Audit
Secretary	Secretary	Secretary	Secretary	2	Audit	Audit
Secretary	Secretary	Secretary	Secretary	2	Audit	Audit
Secretary	Secretary	Secretary	Secretary	2	Audit	Audit
Secretary	Secretary	Secretary	Secretary	2	Audit	Audit
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Secretary	Secretary	Secretary	Secretary	2	Audit</	