Internal Audit Check list			
MANAGEMENT REVIEW			
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SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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.	ISSues Regular review + management meetings
VST Ltd ISO9001:2015 4.1	**Understanding the organization and its context** The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.	Marketing Jobs list ISSues R+D research feedback investments. ✗ check we cover all this
VST Ltd ISO9001:2015 4.2	**Understanding the needs and expectations of interested parties** Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:	

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	a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements.	Interests
VST Ltd ISO9001:2015 4.3	**Determining the scope of the quality management system** The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.	Interests Roles + Response. Issues + Key leading
VST Ltd ISO9001:2015 5.1.1	**General** Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; 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; c) ensuring the integration of the quality management system requirements into the organization's business processes;	management review. Issues

	d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to "business" in this International Standard 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.	Roles + Response. Issues + feedback meetings
VST Ltd ISO9001:2015 6.1	When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.	Risk assessments Roles + Resp. Intranet.
VST Ltd ISO9001:2015 6.1.2	The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions.	Issues. Management Review.

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	Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.	
VST Ltd ISO9001:2015 7.1.1 General	**General** The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from external providers.	Reviews issues Roles + Resp.
VST Ltd ISO9001:2015 9.2.2	The organization shall: 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; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. NOTE See ISO 19011 for guidance.	Audit Calendar management Review Board meeting Doc index

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VST Ltd ISO9001:2015 9.3.2	**Management review inputs** 9.3.2 Management review inputs The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) information on the performance and effectiveness of the quality management system, including trends in: 1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement.	Issues + interstabs. Issues Training manager Barcoding Doc index staff questionaires
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.	meetings - management review
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.	Roles + Responsibilities
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).	Management Reviews Internals. Doc index
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.	Internals Regular Reviews B/code tracking
Viamed Ltd ISO13485:2016 5.1	**Management commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:	

	a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; d) conducting management reviews; e) ensuring the availability of resources.	management Reviews intrastats.
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.	intrastats.
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	Issues Rolling tasks + Audits Doc index
Viamed Ltd ISO13485:2016 5.6.2 Review input	**General** 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;	Intrastats. Audits + Reviews.

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	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 5.6.3	**Review output** The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to: a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; b) improvement of product related to customer requirements; c) changes needed to respond to applicable new or revised regulatory requirements; d) resource needs.	Dcc nchs + Issues Management Review.
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.	Audit Calendar. Intranets Doc index management Review.

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	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.	Doc index issues
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.	management Review

Extra Questions?

Question	Response	Y/N
Check the Review is carried out timely. Task 746 Meeting Minutes should be Attached to Latest Issue # 135684		Y
Verify that all relevant persons were present. See minutes at the bottom		Y

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Check that the review was carried out to the preset agenda. As per Vop 13	Agenda checked	Y
Is this agenda adequate? See any other business see if other sections should be added?		Y
Check that an action plan is generated from the review. Check Section g Recommendations or improvement , and if there any further linked issues to the primary issue.	Follow on Items	Y
Check that actions are completed in a timely manner.		Y
Are minutes retained from the review? Are the minutes attached to the issue		Y
Can these minutes be accessed readily?		Y

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Sub Processes Linked to Audit 18

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

Share Holder

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7834 - ***History/Details*** Shareholder review of the Financial position of the Companies	Financial Review	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	none - this is a subjective review by the share holders	733 Share Holder	769 Managing Director	3	1	3	Task 1M Audit 3M

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Managing Director

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
22 - *History/Details* Ensure the company policys are still current and upto date	Company Policys	22684 VM3COP00.00 Viamed Quality Statement policy and objectives 27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	document should be within its expiry date and reviewed yearly	300 Managing Director		1	1	1	Task 12M
23 - *History/Details* Ensure the company Objects are still current and upto date	Company Objectives	22684 VM3COP00.00 Viamed Quality Statement policy and objectives 22062 VM3COP00.00 VST Quality Statement policy and objectives 27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data 22429 Viamed Top Level Quality Objectives		300 Managing Director					Task 12M
26 - *History/Details* Overview of the Company using various data Reporting Screens	Company Resources	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	none - this is a subjective review by the Managing Director	114 Managing Director		3	1	3	Task 1M
27 - *History/Details* To review and close all automatic rolling Issues. Including all rolling tasks and audits	Management Reviews And Quality Audits	16995 VM3COP27.17 Complete Auto_calender Issues 27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	Review the Management Review Rolling Issues page, ensure they are being reviewed monthly	290 Managing Director	775 Company Secretary	4	1	4	Task 1W Audit 6M
30 Responsibility of notifying MHRA	MHRA Licences And Notifications	27244 VOP 02 Personnel and Responsibility , Staff and Staffing				1	1	1	

of product recalls, and registrations of products		Issues, Training, Roles and Tasks						
31 Notifying notified bodies if there are major changes to the QMS system, Or product recalls	Notified Body Notifications	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks			1	1	1	
32 - ***History/Details*** Complete the CMDCAS Paperwork once per year to Keep the Licence to sell in canada	MDALL Listings	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	NO LONGER KEEP THIS CERTIFICATE	49 Managing Director	1	0		Task 12M
NO LONGER KEEP THIS CERTIFICATE								
55 - *History/Details* Business Continuity Plan	Business Continuity Plan	9546 VM3COPxx Business Continuity Plan 27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	reviewed within the last year	266 Managing Director	1	1	1	Task 12M
6861 - *History/Details* Non Minuted Management discussions on issues	Management Meeting Review Weekly Meeting	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	meetings - host meeting - management meeting review date of last meeting. Check done regularly - monthly	456 Managing Director	4	1	4	Task 1W
7057	Complaints and Vigilance Notifications	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks						
7070 - *History/Details*	Management Review	27178 VOP 13 Process Monitoring,	none - this is a subjective	83	2	1	2	Task

#154305 ✓

#138105 ✓

#160552 ✓

#157775 x in terms.

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To discuss any problems, to assess work load and staffing. To review issues.		System Reviews, Audits, Management Review, Analysis Data 24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd 24129 VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd	review by the Management of the current state of staffing / workload etc.	Managing Director				3M
7874 - ***History/Details*** To Ensure we have the latest version of Med Dev 2.12. and update management if its been updated	Review For Latest Version Med Dev 2.12.	24121 VOP 10 Non Conformance, Corrective and Preventive Actions 24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd 13044 MEDDEV 2.12/1 2012 rev 8 Surveillance	Med Dev document is current	128 Managing Director	1	1	1	Task 12M
7876 - ***History/Details*** To review Route map VIAMED 13485:2016 and VST 9001:2015 See if a new Summary sheet needs producing, print new PDF, and upload on top of the old summary	Maintain Update Of ISO Route Maps	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	If an update is required it should be less than 2 weeks old. Page will indicate Requires Update 22 Aug 2018 1534754042	804 Managing Director	805 Company Secretary	2	1	2	Task 1W Audit 1M
7877 - ***History/Details*** To Plan for disaster	Disaster Planning	14768 VM3COP60.04 Viamed Disaster Planning	make sure we have a disaster plan that has been reviewed in the last 12 months.	806 Managing Director		1	4	4	Task 12M
7878 - ***History/Details***	Review Possible	27178 VOP 13 Process Monitoring,		807		3	3	9	Task

Review possible legal / regulator changes that might affect Viamed / VST	Upcoming Regulation Changes	System Reviews, Audits, Management Review, Analysis Data		Managing Director					3M
7890 - *History/Details* To get the next years UPS zone and areas and Pricing Import into intrastats, No formal procedure as UPS keep changing style and layout, can be done manually	New UPS Rates Needs Checking	24730 VOP 03 Contract Review, Enquires, Office Processes	Check the new information has been added to the system. Check last updated date and new pricing date	42 Managing Director #136608 ✓		2	1	2	Task 12M
7895 - *History/Details* To conitune our FDA registration (for the Apgar timer) **ISO Controller**	FDA Device Establishment Registration	7026 FDA Registration Owner Number	Check we are listed on the FDA Website,	825 Managing Director #157856 ✓		1	1	1	Task 12M

Process Scope	**Brief Description**	**Responsibility/Procedure/Training**	**Measurable Objective**	**Task**	**Audit**	**Freq**	**Risk**	**Overall**	**Action**
29 Annual license check, ensure no changes to Products licenced through CMDCAS, and Issue CMDCAS a statement that No changes have occured. Certificate will go out of date 1st November,	CMDCAS Updates And Licences	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks		49 Managing Director #154305 ✓		1	3	3	Task 12M

Check Canadian Gazette for Latest Version of the MDR 5889 To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits	Audit And Task - Audit	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	#160397 x interms 290 Managing Director	4	1	4	Task 1W
6871 - ***History/Details*** Not yet Applied Rolling Issue to see if we should apply this standard in the future	ISO14001 Environmental management systems	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	#15575 ✓ 748 Managing Director	1	1	1	Task 12M
7744 - ***History/Details*** FDA registration and the CMDCAS products In order to sell in the USA / Canada Markets products need to be registered with the FDA.	FDA Device Establishment Registration And Listing	27438 VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control	#155509 ✓ 565 Managing Director	1	1	1	Task 12M
7833 - ***History/Details*** To Remind Staff of the Importance of the ISO systems and they should be following the procedures	Importance Of Effective Quality Management	22684 VM3COP00.00 Viamed Quality Statement policy and objectives 22062 VM3COP00.00 VST Quality Statement policy and objectives	#155650 ✓ 732 Managing Director	2	1	2	Task 6M

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7888 - *History/Details* Ensure All Sub Processes are linked to a VOP and an Audit.	Review Processes Linked To VOPs And Audits	23527 VOP 12 Training 27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	159168	818 Managing Director	819 Company Secretary	3	1	3	Task 1M Audit 12M	✓ 159908 ✓
7895 - *History/Details* To conitune our FDA registration (for the Apgar timer) **IT Controller**	FDA Device Establishment Registration	7026 FDA Registration Owner Number	Check we are listed on the FDA Website,	825 Managing Director		1	1	1	Task 12M	157856 ✓

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action	
6813 - *History/Details* Ensure the turnover report is accurate **Warehouse Team Leader**	Management Meeting Turnover Report	16942 VM3COP27.13 Intrastats to Opera Turnover Checking 23322 VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment	160500 ✓	459 Managing Director	460 Company Secretary	3	1	3	Task 1M Audit 12M	146512 ✓

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action	
7753 - *History/Details* To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse. **Audits**	Management Meeting Warehouse	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	159127 X In terms due Now	589 Managing Director	590 Company Secretary	3	1	3	Task 1M Audit 3M	157654 X Interms.

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action

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156747 x items

7886 - *History/Details*
To carry out Audit 18 Management Review Viamed

Audit 18 Management Review Viamed

27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data

21 Company Secretary	1	2	2	Audit 12M	This Audit

7887 - *History/Details*
To carry out Audit 18 Management Review VST

Audit 18 Management Review VST

27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data

188 Company Secretary	1	2	2	Audit 12M	

156658 x items

Office Processes

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7750 - *History/Details* Meeting between management and office team leader to discuss improvement of systems and address any issues	Meeting With Management	23527 VOP 12 Training		275 Managing Director 158800 ✓		3	1	3	Task 1M
7793 - *History/Details* A meeting is arranged between the office team leader and their team either as a group or individiually when necessary	Team Review Meeting	23527 VOP 12 Training		639 Company Secretary		3	1	3	Task 1M