Internal Audit Check list

VIAMED LTD MANAGEMENT REVIEW

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Audit Date	10-11-25	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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.	Doc index Roles + tasks
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).	Roles + tasks management Renew Route map
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.	Roles + tasks Route map Tech files
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.	Procedures meeting Roles + tasks Doc index
Viamed Ltd	**Quality policy**	

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ISO13485:2016 5.3	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.	Management review Route Map Doc index Roles + tasks
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.	Procedures Doc index Issues management review Roles + tasks
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; 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.	management review Roles + tasks Route Map Audit Calendar
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.	Doc index management review QA System
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 esablished by the organization, and applicable regulatory requirements;	Audit calendar Route map.

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	b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. 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.	Doc index Roles + tasks Management Review
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

	Question	**Response**	**Y/N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding NO non conformances	Y
2	Check the Review is carried out in a timely manner. Task 746 and Task 1094. 379089 underway VST 2025 371466 Meeting Minutes should be attached to latest Issue. VST 345110 2024 VIA336857 2024	underway 2025 VIA	Y
3	Verify that all relevant persons were present. See minutes at the bottom.		Y
4	Check that the review was carried out to the preset agenda. As per VOP 13.		Y
5	Is this agenda adequate? Look at any other business, do any other sections need to be added?	Reviewed in meeting environmental header added.	Y

	List and issue any needed.		
6	Check that an action plan is generated from the review. Check Section – Recommendations or improvement, and if there any further linked issues to the primary issue.		Y
7	Check that actions are completed in a timely manner.		Y
8	Are minutes retained from the review? Are the minutes attached to the issue		Y
9	Can these minutes be accessed readily?		Y

Sub Processes Linked to Audit 18

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

List Processes Per Title

Clone from Docid

Share Holder					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7834** The review the Financial requirements	Task: 733 381329 ✓ Managing Director Audit :769 377033 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M		
Managing Director					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **22** Ensure the company policys are still current and upto date	Task: 300 373456 ✓ Managing Director Audit ~~1~~063	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID **23** Ensure the company Objects are still current and upto date	Task: 300 373656 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M		

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PROCESSID **26** Overview of the Company using various data Reporting Screens	Task: 114 380039 ✓ Managing Director Audit :	Freq 3 Risk 1 Overall 3	Task 1M			
PROCESSID **27** To review and close all automatic rolling Issues. Including all rolling tasks and audits	Task: 290 381299 ✓ Managing Director Audit :775 378385 ✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1W Audit 6M			
PROCESSID **32** Complete the CMDCAS Paperwork once per year to Keep the Licence to sell in canada NO LONGER KEEP THIS CERTIFICATE	Task: 49 375290 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M			
PROCESSID **55** Business Continuity Plan	Task: 266 355537 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M			
PROCESSID **6861** Non Minuted Management discussions on issues	Task: 456 381530 ✗ Managing Director Underway Audit :	Freq 2 Risk 1 Overall 2	Task 1W			
PROCESSID **7070** To discuss any problems, to assess work load and staffing. To review issues.	Task: 83 379623 ✓ Managing Director Audit :	Freq 2 Risk 1 Overall 2	Task 3M			
PROCESSID **7874** To Ensure we have the latest version of Med Dev 2.12. and update management if its been updated	Task: 128 377797 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M			
PROCESSID **7876** 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	Task: 804 381570 ✓ Managing Director Audit :805 381121 ✓ Company Secretary	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M			
PROCESSID **7877** To Plan for disaster	Task: 806 378660 ✓ Managing Director Audit :	Freq 1 Risk 3 Overall 3	Task 12M			
PROCESSID **7878** Review possible legal / regulator changes that might affect Viamed / VST	Task: 807 378767 ✓ Managing Director Audit :	Freq 1 Risk 3 Overall 3	Task 3M			
PROCESSID **7890** To get the next years UPS zone and areas and Pricing Import into intrastats, No formal procedure as UPS keep changing style and	Task: 42 350258 ✓ Managing Director Audit :1070 356092 ✓	Freq 2 Risk 1 Overall 2	Task 12M Audit 12M			

layout, can be done manually	Company Secretary				
PROCESSID **7895** To conitune our FDA registration (for the Apgar timer)	Task: 825 379689 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID **7972** To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13 *Note was linked to Viamed managment headers relinked in 2025	Task: 1094 379089 Managing Director × Audit : Underway	Freq 1 Risk 1 Overall 1	Task 12M		
Director 1 (Derek)					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*Notes	
PROCESSID **8018** Rolling Issue for Notes During the Weekly Meeting To discuss any problems, to assess work load and staffing. To review issues.	Task: 1193 381590 Managing Director × Audit : in terms	Freq 1 Risk 1 Overall 1	Meeting 1W		
ISO and Compliance Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*Notes	
PROCESSID **29** Annual license check, ensure no changes to Products licenced through CMDCAS, and Issue CMDCAS a statement that No changes have occured. NO LONGER KEEP THIS CERTIFICATE Certificate will go out of date 1st November, Check Canadian Gazette for Latest Version of the MDR	Task: 49 375290 ✓ Managing Director Audit :	Freq 1 Risk 3 Overall 3	Task 12M		
PROCESSID **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	Task: 290 381299 ✓ Managing Director Audit :	Freq 4 Risk 1 Overall 4	Task 1W		
PROCESSID **6871** Not yet Applied Rolling Issue to see if we should apply this standard in the	Task: 748 376379 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M		

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future	Audit :					
PROCESSID **7744** FDA registration and the CMDCAS products In order to sell in the USA / Canada Markets products need to be registered with the FDA.	Task: 565 376478✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M			
PROCESSID **7833** To Remind Staff of the Importance of the ISO systems and they should be following the procedures	Task: 732 376738✓ Managing Director Audit :	Freq 2 Risk 1 Overall 2	Task 6M			
PROCESSID **7888** Ensure All Sub Processes are linked to a VOP and an Audit.	Task: 818 381572✓ Managing Director Audit :819 348753✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M			
PROCESSID **7895** To conitune our FDA registration (for the Apgar timer)	Task: 825 379689✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M			
PROCESSID **7977** To review the Agenda of the Management review. Make sure no headers are missed that should be being discussed. Make sure Objectives are appropriate and effective.	Task: 1100 371677✓ Company Secretary Audit :1101 376499✓ Managing Director	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M			
PROCESSID **7978** To Regulatory Requirements and a Review of QC21 form template. To ensure they are up to date to the current standards review Qc 21 Form to ensure it is still appropriate and valid	Task: 48 379031✓ Managing Director Audit :	Freq 1 Risk 3 Overall 3	Task 12M			
PROCESSID **7979** To review the QC 21 form to make sure it is fit for purpose and covers all the areas we need to assess when filling in this form	Task: 1102 370978✓ Managing Director Audit :	Freq 1 Risk 2 Overall 2	Task 12M			
PROCESSID **7980** Review the Government Website For Applicable Required Standards ISO 9001 Check if any other standards have been introduced that may have an affect on the company www.gov.uk European Commission harmonised standards to check documentation upto date http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm	Task: 1103 381016✓ Managing Director Audit :	Freq 1 Risk 2 Overall 2	Task 12M			
PROCESSID **7981** To review monthly any changes, to any processes, for risks to ISO systems.	Task: 1104 381582✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M			

	Audit :1105 379711 ✓ Company Secretary				
PROCESSID **8036** To review any new rolling future issues check they have a processed it is linked to. Make sure it not duplicated	Task: 1234 367656 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 6M		
IT Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **6813** Ensure the turnover report is accurate	Task: 459 380739 ✓ Managing Director Audit :460 366101 ✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M		
PROCESSID **7918** To backup Jeans files NO LONGER REQUIRED JEAN DOES NOT HAVE FOLDER ANYMORE	Task: ~~923~~ Audit :	Freq 1 Risk 1 Overall 1			
Marketing Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **8094** Just a heading to enable a rolling Task for Issues to link to a Meeting With DL	Task: 1293 381133 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 1W		
Sales Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **8072** Quarterly Sales and Marketing Meeting Due BSI REgulation meeting required, To Include UK Sales Staff, Export Sales Staff, and Sales Director	Task: 81 373968 ✓ Director 3 (Steve) Audit :	Freq 1 Risk 1 Overall 1	Task 3M		
PROCESSID **8073** Quarterly Stock Meeting Due - Full Stock Meeting Due	Task: 82 376697 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 3M		
Warehouse Team Leader					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7753**	Task: 589 381555 ✗ in terms	Freq 3	Task 1M		

To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse.	Managing Director Audit :590 379426✓ Company Secretary	Risk 1 Overall 3	Audit 3M			
UK Sales Controller						
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes	
PROCESSID **8026** To review competitor automotive prices	Task: 1210 381026✓ Marketing Processes Audit :	Freq 1 Risk 1 Overall 1	Task 1M			
Human Resources						
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes	
PROCESSID **7964** To check the Roles and tasks tables for any gaps /red crosses Fill in the missing information where needed.	Task: 1065 379438✓ Company Secretary Audit :1066 368503✓ Managing Director	Freq 1 Risk 2 Overall 2	Task 3M Audit 12M			
PROCESSID **8025** Review the below statement and make sure it is still valid and correct. `Viamed Group of companies does not involve the large-scale use of special category or criminal offence data. We also only occasionally process low risk data of individuals in the EU. We do not need to appoint a EU European representatives.` With this in mind we have reasoned we are not required to appoint any EU European representatives in EU member states.	Task: 1208 357989✓ Company Secretary Audit :1209 362669 ✓ Managing Director	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M			
Data Protection Officer						
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes	
PROCESSID **7912** Review The Personel Information We Collect Or Store, is the personal information that we collect and store - relevant, accurate and not excessive.	Task: 912 377459✓ Company Secretary Audit :	Freq 1 Risk 3 Overall 3	Task 12M			
PROCESSID **7913** To Review the personnel files to check we remove old data to stay within the GDPR	Task: 913 378168✓ Company Secretary Audit :	Freq 1 Risk 1 Overall 1	Task 3M			

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Audits					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7886** To carry out Audit 18 Management Review Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :21 378231 Company Secretary Audit	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID **7887** To carry out Audit 18 Management Review VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: 378136 Audit :188 Company Secretary Audit	Freq 1 Risk 2 Overall 2	Audit 12M		
Office Processes					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7750** Meeting between management and office team leader to discuss improvement of systems and address any issues	Task: 275 380361 Managing Director X Audit :	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID **7793** Duplicate Issue needs process removing see processid 7750	Task; ~~639~~ Audit :	Freq 1 Risk 1 Overall 1			

Rolling Tasks Linked to Document :Task (275) Task (639) Task (290) Task (589) Task (459) Task (456) Task (733) Task (300) Task (114) Task (266) Task (49) Task (748) Task (565) Task (732) Task (128) Task (804) Task (806) Task (807) Task (21) Task (188) Task (83) Task (42) Task (818) Task (825) Task (912) Task (913) Task (923) Task (1065) Task (1100) Task (48) Task (1102) Task (1103) Task (1104) Task (1094) Task (1193) Task (1210) Task (1208) Task (1234) Task (81) Task (82) Task (1293)