

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 1 of 15
Audit Date	28-11-23	Auditor Helen Lamb	

VST

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.5.1.1	<p>General</p> <p>Top management shall demonstrate leadership and commitment with respect to the quality management system by:</p> <ul style="list-style-type: none"> 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; 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. <p>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.</p>	<p>management review Feedback Roles + tasks objectives procedures H + S</p>
VST Ltd ISO9001:2015 5.5.2.1	<p>Establishing the quality policy</p> <p>Top management shall establish, implement and maintain a quality policy that:</p> <ul style="list-style-type: none"> a) is appropriate to the purpose and context of the organization and supports its strategic direction; b) provides a framework for setting quality objectives; c) includes a commitment to satisfy applicable requirements; d) includes a commitment to continual improvement of the quality management system. 	<p>Review meetings objectives</p>

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 2 of 15
Audit Date		Auditor	

VST Ltd ISO9001:2015 5.6.2.2	When planning how to achieve its quality objectives, the organization shall determine: a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated.	Feedback management Review Meeting of objectives
VST Ltd ISO9001:2015 5.7.5.1	General 7.5.1 General The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management system can differ from one organization to another due to: — the size of organization and its type of activities, processes, products and services; — the complexity of processes and their interactions; — the competence of persons.	Route map VOIP Roles + tasks Audits
Viamed Ltd ISO13485:2016 4.1.3	Quality management system For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).	
Viamed Ltd ISO13485:2016 4.1.4	Quality management system For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this	

28/11/2023 Page 2 of 15

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 4 of 15
Audit Date		Auditor	

Viamed Ltd ISO13485:2016 5.4.2	Quality management system planning Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	
Viamed Ltd ISO13485:2016 5.5.1	Responsibility and authority Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.	

	manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.	
Viamed Ltd ISO13485:20 16.5.2	Management representative Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes: a) ensuring that processes needed for the quality management system are documented; b) reporting to top management on the effectiveness of the quality management system and any need for improvement; c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.	
Viamed Ltd ISO13485:20 16.5.6.3	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.	
Viamed Ltd ISO13485:20 16.6.1	Provision of resources The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness; b) meet applicable regulatory and customer requirements.	
Viamed Ltd ISO13485:20	Internal audit The organization shall conduct internal audits at planned intervals to	

28/11/2023 Page 4 of 15

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 5 of 15
Audit Date		Auditor	

16.8.2.4	determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.	
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Viamed Ltd ISO13485:20 16.8.3.4	Rework The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.	
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Viamed Ltd ISO13485:20 16.8.5.3	Records or rework shall be maintained (see 4.2.5).	/
	<p>Preventive action</p> <p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.</p> <p>The organization shall document a procedure to describe requirements for:</p> <p>a) determining potential nonconformities and their causes;</p> <p>b) evaluating the need for action to prevent occurrence of nonconformities;</p>	

28/11/2023 Page 5 of 15

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 6 of 15
Audit Date		Auditor	

	<p>c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;</p> <p>d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;</p> <p>e) reviewing the effectiveness of the preventive action taken, as appropriate.</p> <p>Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).</p>	
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	INTERNAL PROCESS VERIFICATION		
	<p>A. Management System:</p> <p>B. Management Responsibility</p> <p>C. Resource Management</p> <p>D. Product Realisation</p> <p>E. Design & Development</p> <p>F. Product Provision</p> <p>G. Process Monitoring</p> <p>The following are questions that should be asked and answered either through Internal audits or at this meeting</p>		
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
	A – MANAGEMENT SYSTEM		
2	Is the Quality Statement Policy and Objectives reviewed annually. ISO – Document Index Task ID (300). Search Issues and review.	most recent issue 304697 up to date	Y
3	Is the process manual up to date. ISO – Document Index Task ID (548). Search Issues and review.	312827 up to date	Y
4	Is VOP / VOP documentation checked prior to formal approval and issue.		Y
5	Check that there is a system in operation for the request for amendments.		Y
6	Verify that amendments are updated electronically and old copies archived.		Y
7	Are sales orientated records filed and archived correctly.	Digital and Automatic attached to contact order	Y

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 7 of 15
Audit Date		Auditor	

8	Has organisation Chart changed. VM3COP02.02 <i>Done 24/8/23</i>	<i>Last update 28 Nov 2022</i>	<i>N</i>
9	Has personnel responsibility descriptions changed. Roles Titles Processes and Procedures ADMIN Over View for complete list		
10	Check that the CE files are maintained by sole responsibility.		<i>Y</i>
11	Check that the Notified body is informed of major changes to Documentation.		<i>Y</i>
12	Check that electronic documents are regularly backed up and secure off site. ISO – Document Index Task ID (452). Search Issues and review.	<i>Last issue 21/5/26</i>	<i>Y</i>
13	Does the management system comprise a series of process controls and are they in place throughout the organisation. Are processes identified.	Intrastats. Audit 10	<i>Y</i>
14	Check the system for its policies and objectives and its control of the above processes and procedures. Is the Standards Manual up to date and does it indicates the company's objectives. Are procedures in place – VM3COP Are they available to all personnel – Doc Index Are other company documents i.e. Technical Drawings, Standards: Operators Manuals etc. also available and controlled – Doc index	Intrastats, Audit 10 Roles and Responsibilities.	<i>Y</i>
15	Are the latest revision of documents controlled by version and date status and are they easily accessible. Is the Managing Director or designate manager still giving final approval for document changes.	Intrastats. Audit 10	<i>Y</i>
16	Has the Business Continuity Plan has expired. ISO – Document Index Task 266.	<i>Last issue 25/05/16</i>	<i>Y</i>
<u>B - MANAGEMENT RESPONSIBILITY</u>			
17	Is Top management showing full commitment to the overall system and are communication lines in place. Manage Review Task 290.	Intrastats, Director in control of QA system <i>Last issue 2/13</i>	<i>Y</i>
18	Are all customer requirements defined and met.	Contract Review Audit 2	<i>Y</i>
19	Are all the processes and objectives, undertaken within the		<i>Y</i>

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 8 of 15
Audit Date		Auditor	

	company, documented in Intrastats and have a procedure. Is it measurable. Check process for measurable task 114 Documented in Staff – Audit of Roles, titles and procedures.	<i>Last issue 311527 ✓</i>	Y
20	Does the person responsible for the management systems have the authority to implement actions and reports directly to top management with the need for these actions	Managing Director	Y
21	Are reviews of the management system undertaken regularly and the results and actions relayed throughout the organisation. Task 290 for weekly review – 313190 ✓ Task 114 for bigger overview – 311527 ✓ Task 746 for total review – 302478 ✓	Issues, Message of Day, company meetings, management meetings, Management weekly reviews	Y
22	Are all required actions undertaken in a timely manner and closed where appropriate.	Intrastats Issues	Y
23	Are all output requirements in such a format that verification against inputs, is applicable and appropriate. Is fitness for Purpose validated and is it measurable. Staff – Audit of Roles, titles and procedures – click into details - review Scope and Risks. To check relevance. Staff – Audit of Roles, titles and procedures check down the page for gaps in the IP 1-6 (end tick boxes)		Y
24	Are actions recorded against verifications completed in a timely and responsible manner.	Intrastats Issues	Y
25	Are design changes recorded and all the relevant information filed in the appropriate places.	Design control Audit 3 Intrastats	Y
<u>C - RESOURCE MANAGEMENT</u>			
26	Has top management established a mechanism for identifying and providing required resources, training etc.	Training Audit 8	Y
27	Does this include existing and new personnel.	Training Audit 8	Y
28	Has top management identified the competency levels and attributes required for existing and new personnel.	Training Audit 8	Y
29	Is the competency of personnel monitored, verified and the appropriate records maintained	Training Audit 8	Y
30	Are personnel responsibilities defined.	Roles and Responsibilities	Y

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 9 of 15
Audit Date		Auditor	

31	Do individuals know their responsibilities, reporting and communicating lines. Each employee has 'My Roles' Link Task 314 - 304933	Intrastats communication ISSUE SORT	Y
32	Verify that all procedures, detail who is responsible for it.		Y
33	Check these roles and responsibilities also include Health & Safety tasks – Health and Safety Controller.		Y
34	Is the need for equipment, plant, services etc. identified and acted upon where necessary. Task 13 Part of audit 19	Production meetings, management meetings Health and Safety Questionnaire. ISSUE 302429 ✓	Y
35	Has the basic working infrastructure been planned with conformity to requirements in mind.	Health & safety Audit 19	Y
36	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	COP/07	Y
37	Are the controls in place, to safeguard customer property, adequate for full protection against loss damage etc.	COP/09	Y
38	Is the process for monitoring and measurement of product in place at all stages throughout the production process.	Production COPs	Y
39	Is the process for control of measuring equipment adequate for the monitoring of product verifications.	Calibration Audit 06	Y
40	Are validity processes in place to safeguard product integrity.	Bar coding traceability	Y
D - PRODUCT REALISATION		No new products at this time	
41	Is the planning process for the realisation of product undertaken at the relevant stages.		Y
42	Does planning identify documentation, testing and other such activities as required and that all appropriate records are maintained.		Y
43	Are all customer requirements being addressed, including statutory and regulatory and that the capabilities are identified to meet those requirements.	Contract Review Audit 02	Y
44	Establish that mechanisms are in place to review all customer requirements prior to any commitments by the organisation.	Contract Review Audit 02	Y
45	Check that there are adequate arrangements for customer communications and feedback.	Contract Review Audit 02	Y
46	Is collation and analysis of all relevant data determined and effective. Is corrective actions identified.		Y
47	Are these actions completed in a timely and adequate manner and are these actions part of continual improvements.		Y
48	Does the organisation have preventive measures in place to		Y

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 10 of 15
Audit Date		Auditor	

	control potential non-conformities.		
49	Are all the above actions are reviewed adequately.		Y
	E - DESIGN & DEVELOPMENT <i>No new Design</i>		
50	Are procedures in place to ensure adequate planning of product design and that all relevant stages are identified.	Design control Audit 3	Y
51	Are the interfaces and assignments of responsibilities identified.	Design control Audit 3	Y
52	Are all input requirements determined. Is the documentation identified.	Design control Audit 3	Y
53	Are all output requirements in such a format, that verification against inputs is applicable and appropriate. Is Fitness for Purpose validated.	Design control Audit 3	Y
54	Are actions recorded against verifications completed in a timely and responsible manner.	Design control Audit 3	Y
55	Are validation processes in place and are they determined in accordance with the relevant requirements.	Design control Audit 3	Y
56	Are design changes recorded and all the relevant information filed in the appropriate places.	Design control Audit 3	Y
	F - PRODUCT PROVISION		
57	Are supplier profiles adequate and appropriate for the organisation. Are they monitored, for their ability to provide the requirements, is this monitoring controlled.	Purchasing Controls (Supplier Performance) Audit 5	Y
58	Is all the required information necessary, forwarded to suppliers in the correct format. Will be system controlled.	Purchasing Controls (Supplier Performance) Audit 5	Y
59	Are goods and services received correct to the requirements stipulated.	Goods Inward Audit 9	Y
60	Are the provisions available, suitable for control of production and service, including procedures and equipment etc.	Production Audit 15	Y
61	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	Production Audit 15	Y
62	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Production Audit 15	Y
63	Is the process for monitoring and measurement of products in place at all stages throughout the production process.	Production Audit 15	Y
64	Is the process, for control of measuring equipment, adequate for the monitoring of product verifications.	Calibration Audit 6	Y
	G - PROCESS MONITORING		
65	Are mechanisms in place to monitor all relevant processes,		Y

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 11 of 15
Audit Date		Auditor	

	including customer satisfaction. Are these verified against known criteria. Check process ID 114 <i>Issue 311527 ✓</i>		Y
66	Are controls in place for non-conforming product and processes. Are adequate to prevent unintended uses.	Goods Inward Audit 9	Y
67	Where non-conforming product / process have been detected is appropriate action taken.	Goods Inward Audit 9	Y
68	Is collation and analysis of all relevant data determined and effective Is corrective actions identified.		Y
69	Are these actions completed in a timely and adequate manner. Are these actions part of continual improvements.		Y
70	Are all the above actions are reviewed adequately. Check process ID 114 <i>Issue 311527 ✓</i>	Annually	Y
71	Are regular analyses undertaken to identify any outstanding requirements.	Intrastats	Y
72	Are necessary changes implemented where and when required.		Y
73	Is any outsourcing done.		NO
74	Check the documented system for its policies, objectives and its control of the above processes and procedures. Intrastats – document index – VM3COP00.00 / VM3COP00.01. Check documents for location of objectives and policies.	Intrastats VM3COP00.00 1d VM3COP00.01 1d	22062 22842 Y
75	Are records of inspections filed.	Audits	Y

List Processes Per Title

Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7837 To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks	743 Managing Director <i>308128 ✓</i>	784 Company Secretary <i>311147 ✓</i>	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID 7845 Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.	745		Freq 1 Risk 1 Overall 1		

Merged into 7729 can close the tasks

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 12 of 15
Audit Date		Auditor	

PROCESSID 7846 To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13	746 Managing Director 302478 ✓	Freq 1 Risk 1 Overall 1	Task 12M
PROCESSID 7848 To Review the Scope of the ISO 9001 / ISO 13485 Standards	749 Managing Director 301761 ✓	Freq 1 Risk 1 Overall 1	Task 12M
PROCESSID 7871 To review the Exclusions / boundaries to ISO 13485:2016 for Viamed	790 Managing Director 302 481 ✓	Freq 1 Risk 1 Overall 1	Task 12M
ISO Controller			
Process Scope	Roll Task	Roll Audit	Risk
PROCESSID 6866 Review the Internal Process and Verification's are suitable for the current standards	55		Action
PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20			Referenced in Document
PROCESSID 7827 To review the Quality policy and check it is still valid and upto date.	301 Managing Director 304679 ✓	Freq 1 Risk 1 Overall 1	Task 12M
PROCESSID 7828 To review the Quality policy and check it is still valid and upto date.	723 Managing Director 304727 ✓	Freq 1 Risk 1 Overall 1	Task 12M
IT Controller			
Process Scope	Roll Task	Roll Audit	Risk
PROCESSID 7701 Amazon Web Services, is an online service, which basically simply provides a Linux PC out on the Web. Viamed uses this, for Web development of Websites: It hosts a working backup of many websites. Viamed / vst / vandagraph etc..	511 Office Processes 311716	✓ in terms	Action
PROCESSID 7755	597 311862	✓ in terms	Referenced in Document
			Task 1M

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 13 of 15
Audit Date		Auditor	

To Send Invoice for online services to Helen	Office Processes		Risk 1 Overall 3	
PROCESSID 7832 Backup of all Sent Emails sent to External Address for Verification	731 Managing Director <i>313060</i>	✓	Freq 1 Risk 1 Overall 1	Task 2W
PROCESSID 7850 Test the Goods out process disabling picking of items not relating to an order	752 Goods Out <i>296716</i>	753 Managing Director <i>297629</i>	Freq 1 Risk 1 Overall 1	Task 9M Audit 12M
PROCESSID 7851 To test intrastats does not allow picking of unprocessed products to live customer orders	754 Goods Out <i>297629</i>	755 Managing Director <i>285253</i>	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M
PROCESSID 7852 To attempt to Scan a product that has gone past its expire date.	756 Goods Out <i>309206</i>	757 Managing Director <i>288429</i>	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID 7853 Warehouse shelves can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders.	759 Goods Out <i>305449</i>	760 Managing Director <i>314083</i>	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M
Test that Order picking cannot pick unsellable stock locations to an Order				
PROCESSID 7854 Software Validation of the production lists.	761 Goods In <i>308130</i>	762 Managing Director <i>311158</i>	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated				
PROCESSID 7855 Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists	761 Goods In <i>308130</i>	762 Managing Director <i>311158</i>	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
PROCESSID 7856 To check order picking cannot pick against an unchecked order	764 Office Processes <i>282043</i>	765 Managing Director <i>314083</i>	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M
PROCESSID 7857 To confirm Software Validation Stock Tracking Check, is functioning as expected	763 Goods In <i>308784</i>	1155 Managing Director <i>288288</i>	Freq 2 Risk 1 Overall	Task 6M Audit 12M

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 14 of 15
Audit Date		Auditor	

PROCESSID 7858 Test the QA System that Staff not trained for QA Office Processes are unable to QA a Product.	766	1175	Freq 1 Risk 3 Overall 3	Task 6M Audit 12M
	20131222✓	2016124✓		
PROCESSID 7861 Software Validating Of Training Documents via Forced Required Reading	768	Managing Director	Freq 1 Risk 2 Overall 2	Task 12M
	305423✓			
PROCESSID 7865 Software Validation of the system: To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit.	779	781	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
	305786✓	301454✓		
PROCESSID 7870 Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report.	789	Managing Director	Freq 1 Risk 1 Overall 1	Task 12M
	304455✓			
PROCESSID 7875 To test document control is working as intended.	802	803	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
	310055✓	311101✓		
PROCESSID 7879 To check the Scheduled Tasks and Audits is working as Intended. To also Check the Out of Date documents is working as Intended.	808	809	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M
	186358✓	310518✓		
PROCESSID 7880 To confirm the out of documents computer software functions as expected flagging out of date items on to the list	808	809	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M
	284305✓	310518✓		
PROCESSID 7881 To compare Opera Live Orders to Intrastats Back order Active List	810		Freq 1 Risk 1 Overall 1	

NO LONGER REQUIRED
Opera is now out of the system

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7723 To carry out Audit 10b Process Verification Viamed		3	Freq 1 Risk 2 Overall 2		

Internal Audit Check list

INTERNAL PROCESS VERIFICATION

Created:	17/May 1995	Audit No 20 Sit With management and Complete this Form	
Revised:	28 November 2023		Page 15 of 15
Audit Date		Auditor	

Now Defunct - See Audit 20

PROCESSID 7730

To carry out Audit 20 Process Verification To Management Viamed

Viamed
Audit

172
Company
Secretary
31/11/1

Freq 1
Risk 2
Overall
2

Audit 12M

PROCESSID 7771

To carry out Audit 10b Process Verification VST

177

Freq 1
Risk 2
Overall
2

Now Defunct - See Audit 20

PROCESSID 7778

To carry out Audit 20 Process Verification To Management VST

VST
Audit

181
Company
Secretary
31/11/16

Freq 1
Risk 2
Overall
2

Audit 12M

VM3COP Procedures Linked to

DOCID Title / Description

133732 QMS Route Map Viamed Ltd ISO13485_2016

