

Internal Audit Check list			
VANDAGRAPH SENSOR TECHNOLOGIES LTD			
PROCESS VERIFICATION TO MANAGEMENT			
Created:	17/May 1995	Audit No 20	
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Audit Date	5-11-2025	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.1.1	<b>General</b> Top management shall demonstrate leadership and commitment with respect to the quality management system by: <ul style="list-style-type: none"> <li>a) taking accountability for the effectiveness of the quality management system;</li> <li>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;</li> <li>c) ensuring the integration of the quality management system requirements into the organization's business processes;</li> <li>d) promoting the use of the process approach and risk-based thinking;</li> <li>e) ensuring that the resources needed for the quality management system are available;</li> <li>f) communicating the importance of effective quality management and of conforming to the quality management system requirements;</li> <li>g) ensuring that the quality management system achieves its intended results;</li> <li>h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;</li> <li>i) promoting improvement;</li> <li>j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.</li> </ul> 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.	Management Review Issues Feedback Rides + tasks HSE Questionnaire Staff meetings Reviews.
VST Ltd ISO9001:2015 5.2.1	<b>Establishing the quality policy</b> Top management shall establish, implement and maintain a quality policy that: <ul style="list-style-type: none"> <li>a) is appropriate to the purpose and context of the organization and supports its strategic direction;</li> <li>b) provides a framework for setting quality objectives;</li> <li>c) includes a commitment to satisfy applicable requirements;</li> <li>d) includes a commitment to continual improvement of the quality management system.</li> </ul>	Objectives meeting header Management Review
VST Ltd ISO9001:201	When planning how to achieve its quality objectives, the organization shall determine:	

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5 6.2.2	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.	management review Feedback meeting objectives
VST Ltd ISO9001:201 5 7.5.1	<b>General</b> 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 Audits VOP's Doc index Roles + tasks CPM Audits

	<b>INTERNAL PROCESS VERIFICATION</b> A. Management System: B. Management Responsibility C. Resource Management D. Product Realisation E. Design & Development F. Product Provision G. Process Monitoring The following are questions that should be asked and answered either through Internal audits or at this meeting		
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding No non Conformances.	Y
	<b>A – MANAGEMENT SYSTEM</b>		
2	Is the Quality Statement Policy and Objectives reviewed annually. ISO – Document Index Task ID (300). Search Issues and review.	Issue 373456 up to date	Y
3	Is the process manual up to date. ISO – Document Index Task ID (548). Search Issues and review.	Issue 378508 up to date	Y
4	Is VOP / VOP documentation checked prior to formal approval and issue.		Y



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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
8	Has organisation Chart changed. VM3COP02.02		NO
9	Has personnel responsibility descriptions changed. Roles Titles Processes and Procedures ADMIN Over View for complete list	SH left Jobs reassigned	Y
10	Check that the CE files are maintained by sole responsibility.		Y
11	Check that the Notified body is informed of major changes to Documentation.		Y
12	Check that electronic documents are regularly backed up and secure off site. ISO – Document Index Task ID (452). Search Issues and review.	issue upto date 379919	Y
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	Y
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.	Y
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	Y
16	Has the Business Continuity Plan has expired. ISO – Document Index Task 266. issue 355537 upto date		Y
	<b><u>B - MANAGEMENT RESPONSIBILITY</u></b>		
17	Is Top management showing full commitment to the overall system and are communication lines in place.	Intrastats, Director in control of QA system	



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	Manage Review Task 290. 379406 ✓ up to date		Y
18	Are all customer requirements defined and met.	Contract Review Audit 2	Y
19	Are all the processes and objectives, undertaken within the 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. 380039 issues up to date		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 ✓ Task 114 for bigger overview ✓ Task 746 for total review Being planned at present	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. No New Design	Design control Audit 3 Intrastats	Y
<b>C - RESOURCE MANAGEMENT</b>			
26	Has top management established a mechanism for identifying and providing required resources, training etc. management	Training Audit 8 Renew	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 Appraisals	Y
29	Is the competency of personnel monitored, verified and the appropriate records maintained	Training Audit 8	Y



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30	Are personnel responsibilities defined.	Roles and Responsibilities	✓
31	Do individuals know their responsibilities, reporting and communicating lines. Each employee has 'My Roles' Link Task 314	Intrastats communication 373629 issues up to date	✓
32	Verify that all procedures, detail who is responsible for it.		✓
33	Check these roles and responsibilities also include Health & Safety tasks – Health and Safety Controller.		✓
34	Is the need for equipment, plant, services etc. identified and acted upon where necessary. Task 13 Part of audit 19 371416 issues up to date	Production meetings, management meetings Health and Safety Questionnaire.	✓
35	Has the basic working infrastructure been planned with conformity to requirements in mind.	Health & safety Audit 19	✓
36	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	COP/07	✓
37	Are the controls in place, to safeguard customer property, adequate for full protection against loss damage etc.	COP/09	✓
38	Is the process for monitoring and measurement of product in place at all stages throughout the production process.	Production COPs	✓
39	Is the process for control of measuring equipment adequate for the monitoring of product verifications.	Calibration Audit 06	✓
40	Are validity processes in place to safeguard product integrity.	Bar coding traceability	✓
<b>D - PRODUCT REALISATION</b>			
41	Is the planning process for the realisation of product undertaken at the relevant stages.		✓
42	Does planning identify documentation, testing and other such activities as required and that all appropriate records are maintained.		✓
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	✓
44	Establish that mechanisms are in place to review all customer requirements prior to any commitments by the organisation.	Contract Review Audit 02	✓
45	Check that there are adequate arrangements for customer communications and feedback.	Contract Review Audit 02	✓
46	Is collation and analysis of all relevant data determined and effective. Is corrective actions identified.		✓
47	Are these actions completed in a timely and adequate manner and are these actions part of continual improvements.		✓
48	Does the organisation have preventive measures in place to		✓



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	control potential non-conformities.		
49	Are all the above actions are reviewed adequately.		✓
	<b><u>E - DESIGN &amp; DEVELOPMENT</u></b> <i>No 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	✓
51	Are the interfaces and assignments of responsibilities identified.	Design control Audit 3	✓
52	Are all input requirements determined. Is the documentation identified.	Design control Audit 3	✓
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	✓
54	Are actions recorded against verifications completed in a timely and responsible manner.	Design control Audit 3	✓
55	Are validation processes in place and are they determined in accordance with the relevant requirements.	Design control Audit 3	✓
56	Are design changes recorded and all the relevant information filed in the appropriate places.	Design control Audit 3	✓
	<b><u>F - PRODUCT PROVISION</u></b>		
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	✓
58	Is all the required information necessary, forwarded to suppliers in the correct format. Will be system controlled.	Purchasing Controls (Supplier Performance) Audit 5	✓
59	Are goods and services received correct to the requirements stipulated.	Goods Inward Audit 9	✓
60	Are the provisions available, suitable for control of production and service, including procedures and equipment etc.	Production Audit 15	✓
61	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	Production Audit 15	✓
62	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Production Audit 15	✓
63	Is the process for monitoring and measurement of products in place at all stages throughout the production process.	Production Audit 15	✓
64	Is the process, for control of measuring equipment, adequate for the monitoring of product verifications.	Calibration Audit 6	✓
	<b><u>G - PROCESS MONITORING</u></b>		
65	Are mechanisms in place to monitor all relevant processes, including customer satisfaction. Are these verified against known criteria. Check process ID 114 <i>380039 issues up to date</i>		✓



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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 380039 / issue up to date	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	Y
75	Are records of inspections filed.	Audits	Y

## Sub Processes Linked to Audit

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

## List Processes Per Title

Managing Director				
Process Scope	Roll Task Roll Audit	Risk	Action	*N
PROCESSID 7837 To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks	Task: 743 376739 / Managing Director  Audit : 784 379685 / Company Secretary	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.  Merged into 7729 can close the tasks	Task: 745  Audit :	Freq 1 Risk 1 Overall 1		

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PROCESSID 7846 To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13	Task: 746 <i>371466</i> Managing Director <i>now due</i> Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7848 To Review the Scope of the ISO 9001 / ISO 13485 Standards	Task: 749 <i>376486</i> Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7871 To review the Exclusions / boundaries to ISO 13485:2016 for Viamed	Task: 790 <i>371470</i> Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
ISO and Compliance Controller				
Process Scope	Roll Task Roll Audit	Risk	Action	*N
PROCESSID 6866 Review the Internal Process and Verification's are suitable for the current standards	Task: 55 Audit :	Freq 1 Risk 1 Overall 1		
PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20				
PROCESSID 7827 To review the Quality policy and check it is still valid and upto date.	Task: 301 <i>373457</i> Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7828 To review the Quality policy and check it is still valid and upto date.	Task: 723 <i>373496</i> Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
IT Controller				
Process Scope	Roll Task Roll Audit	Risk	Action	*N
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..	Task: 511 <i>377820</i> Office Processes Audit :	Freq 3 Risk 1 Overall 3	Task 12M	
PROCESSID 7755 To Send Invoices for online services to Helen every 12 months on the issue	Task: 597 <i>377835</i> Office Processes Audit :	Freq 3 Risk 1 Overall 3	Task 12M	
PROCESSID 7832 Backup of all Sent Emails sent to External Address for Verification	Task: 731 <i>380072</i> Office Processes Audit :1243 <i>378274</i>	Freq 1 Risk 1 Overall 1	Task 2W Audit 12M	



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PROCESSID 7850 Test the Goods out process disabling picking of items not relating to an order	Managing Director Task: 752 374024 Goods Out Audit :753 354355 Managing Director	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	Task: 754 366 887 Goods Out Audit :755 354356 Managing Director	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.	Task: 756 377841X Goods Out in terms Audit :757 357131 Managing Director	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.  Test that Order picking cannot pick unsellable stock locations to an Order	Task: 759 374026 Goods Out Audit :760 348619 Managing Director	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M
PROCESSID 7854 Software Validation of the production lists.  By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated	Task: 761 37641 Goods In Audit :762 379682 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
PROCESSID 7855 Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists	Task: 761 37641 Goods In Audit :762 379682 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
PROCESSID 7856 To check order picking cannot pick against an unchecked order	Task: 764 350940 Office Processes Audit :765 348620 Managing Director	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M
PROCESSID 7857 To confirm Software Validation Stock Tracking Check, is functioning as expected	Task: 763 377454 Goods In Audit :1155 357163 Managing Director	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M
PROCESSID 7858 Test the QA System that Staff not trained for QA are unable to QA a Product.	Task: 766 365 827 Office Processes Audit :1175 355071	Freq 1 Risk 3 Overall 3	Task 6M Audit 12M



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PROCESSID 7861 Software Validating Of Training Documents via Forced Required Reading	Managing Director Task: 768 377169 Managing Director Audit :	Freq 1 Risk 2 Overall 2	Task 12M	
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.	Task: 779 377455 Managing Director Audit : 781 378013 Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID 7870 Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report.	Task: 789 378259 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7875 To test document control is working as intended.	Task: 802 378525 Managing Director Audit : 803 379686 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
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.	Task: 808 353229 Managing Director Audit : 809 379075 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M	
PROCESSID 7880 To confirm the out of documents computer software functions as expected flagging out of date items on to the list	Task: 808 353229 Managing Director Audit : 809 379075 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M	
PROCESSID 7881 To compare Opera Live Orders to Intrastats Back order Active List  NO LONGER REQUIRED Opera is now out of the system	Task: 810 Audit :	Freq 1 Risk 1 Overall 1		
Audits				
Process Scope	Roll Task Roll Audit	Risk	Action	*N
PROCESSID 7723 To carry out Audit 10b Process Verification Viamed  Now Defunct - See Audit 20	Task: Audit : 3	Freq 1 Risk 2 Overall 2		
PROCESSID 7730 To carry out Audit 20 Process Verification To Management Viamed	Task: Audit : 172 379629 * sudit	Freq 1 Risk 2 Overall 2	Audit 12M	



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Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.	Company Secretary			
If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.				
PROCESSID 7771 To carry out Audit 10b Process Verification VST	Task:	Freq 1 Risk 2 Overall 2		
Now Defunct - See Audit 20	Audit : 177			
PROCESSID 7778 To carry out Audit 20 Process Verification To Management VST	Task:	Freq 1 Risk 2 Overall 2	Audit 12M	
Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.	Audit : 181 Company Secretary			
If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	379630x Audit			

Rolling Tasks Linked to Document : Task (3) Task (172) Task (177) Task (181)  
 Task (55) Task (301) Task (723) Task (743) Task (745) Task (746) Task (749)  
 Task (790) Task (511) Task (597) Task (731) Task (752) Task (754) Task (756)  
 Task (759) Task (761) Task (764) Task (763) Task (766) Task (768) Task (779)  
 Task (789) Task (802) Task (808) Task (810)