

# Internal Audit Check list

## VANDAGRAPH SENSOR TECHNOLOGIES LTD MANAGEMENT REVIEW

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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 10.3	<b>Continual improvement</b> 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.	Management Renew Doc index
VST Ltd ISO9001:2015 4.1	<b>Understanding the organization and its context</b> 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.	Management Renew Supplier Renewals QA System Marketing index Feedback
VST Ltd ISO9001:2015 4.2	<b>Understanding the needs and expectations of interested parties</b> 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: 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.	Interested parties Roles + titles External parties QMS
VST Ltd ISO9001:2015 4.3	<b>Determining the scope of the quality management system</b> 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	Scope 9001 Management Renew Feedback Doc index Training Records Supplier Renew



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	<p>organization determines is not applicable to the scope of its quality management system.</p> <p>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.</p>	<p>Calibration index</p> <p>Marketing index</p>
VST Ltd ISO9001:2015 5.1.1	<p><b>General</b></p> <p>Top management shall demonstrate leadership and commitment with respect to the quality management system by:</p> <p>a) taking accountability for the effectiveness of the quality management system;</p> <p>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;</p> <p>c) ensuring the integration of the quality management system requirements into the organization's business processes;</p> <p>d) promoting the use of the process approach and risk-based thinking;</p> <p>e) ensuring that the resources needed for the quality management system are available;</p> <p>f) communicating the importance of effective quality management and of conforming to the quality management system requirements;</p> <p>g) ensuring that the quality management system achieves its intended results;</p> <p>h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;</p> <p>i) promoting improvement;</p> <p>j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.</p> <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>Feedback</p> <p>Roles + titles</p> <p>Management Reviews</p> <p>H+S questionnaire</p> <p>Renew meetings</p>
VST Ltd ISO9001:2015 6.1	<p>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:</p> <p>a) give assurance that the quality management system can achieve its intended result(s);</p> <p>b) enhance desirable effects;</p> <p>c) prevent, or reduce, undesired effects;</p> <p>d) achieve improvement.</p>	<p>Roles + titles</p> <p>Review of Risk.</p> <p>Renew meetings</p>
VST Ltd ISO9001:2015 6.1.2	<p>The organization shall plan:</p> <p>a) actions to address these risks and opportunities;</p> <p>b) how to:</p> <p>1) integrate and implement the actions into its quality management system processes (see 4.4);</p> <p>2) evaluate the effectiveness of these actions.</p> <p>Actions taken to address risks and opportunities shall be proportionate to</p>	<p>Company Risk assessments</p> <p>Review of Risk.</p> <p>Management Review</p>



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	<p>Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.</p> <p>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.</p> <p>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.</p>	<p>Rdes + titles</p> <p>External partners</p>
VST Ltd ISO9001:2015 7.1.1 General	<p><b>General</b></p> <p>The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.</p> <p>The organization shall consider:</p> <p>a) the capabilities of, and constraints on, existing internal resources;</p> <p>b) what needs to be obtained from external providers.</p>	<p>Feedback meetings</p> <p>Rdes + titles</p>
VST Ltd ISO9001:2015 9.2.2	<p>The organization shall:</p> <p>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;</p> <p>b) define the audit criteria and scope for each audit;</p> <p>c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;</p> <p>d) ensure that the results of the audits are reported to relevant management;</p> <p>e) take appropriate correction and corrective actions without undue delay;</p> <p>f) retain documented information as evidence of the implementation of the audit programme and the audit results.</p> <p>NOTE See ISO 19011 for guidance.</p>	<p>Audit Calendar</p> <p>Rowle Msp</p> <p>Management Review</p> <p>Doc index</p>
VST Ltd ISO9001:2015 9.3.2	<p><b>Management review inputs</b></p> <p>9.3.2 Management review inputs</p> <p>The management review shall be planned and carried out taking into consideration:</p> <p>a) the status of actions from previous management reviews;</p> <p>b) changes in external and internal issues that are relevant to the quality management system;</p> <p>c) information on the performance and effectiveness of the quality management system, including trends in:</p> <p>1) customer satisfaction and feedback from relevant interested parties;</p> <p>2) the extent to which quality objectives have been met;</p> <p>3) process performance and conformity of products and services;</p> <p>4) nonconformities and corrective actions;</p> <p>5) monitoring and measurement results;</p> <p>6) audit results;</p> <p>7) the performance of external providers;</p> <p>d) the adequacy of resources;</p>	<p>Management Review</p> <p>Rdes + titles</p> <p>Feedback</p> <p>ISSUES</p> <p>PMs</p> <p>QA system</p> <p>QC 21 forms</p>



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	e) the effectiveness of actions taken to address risks and opportunities; (see 6.1); f) opportunities for improvement.	
VST Ltd ISO9001:2015 9.3.3	<b>Management review outputs</b> 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.	Route map management Review.

	Question	Response	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
2	Check the Review is carried out in a timely manner. Task 746 and Task 1094. 345110 ✓ - Jan 24 336857 ✓ Meeting Minutes should be attached to latest Issue.		Y
3	Verify that all relevant persons were present. See minutes at the bottom.	all present	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? List and issue any needed.	Renewed in meeting issues sent to add this	Y
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.	Issues	Y
8	Are minutes retained from the review? Are the minutes attached to the issue		Y
9	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.

#### 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 344451✓ Managing Director  Audit :769 342718✓ 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 339088✓ Managing Director  Audit X063	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID 23 Ensure the company Objects are still current and upto date	Task: 300 339088✓ Managing Director  Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID 26 Overview of the Company using various data Reporting Screens	Task: 114 345962✓ 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 346231✓ Managing Director  Audit :775 344201✓ 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	Task: 49 340942✓ Managing Director  Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
NO LONGER KEEP THIS CERTIFICATE					
PROCESSID 55	Task: 266 320648✓	Freq 1	Task 12M		



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Business Continuity Plan	Managing Director	Risk 1 Overall 1			
PROCESSID 6861 Non Minuted Management discussions on issues	Audit : Task: 456 346516 ✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 1W		
PROCESSID 7070 To discuss any problems, to assess work load and staffing. To review issues.	Audit : Task: 83 34553 ✓ Managing Director	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	Audit : Task: 128 343609 ✓ Managing Director	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	Audit : Task: 804 346548 ✓ Managing Director  Audit :805 344338 ✓ Company Secretary	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M		
PROCESSID 7877 To Plan for disaster	Audit : Task: 806 344457 ✓ Managing Director  Audit : Terms	Freq 1 Risk 3 Overall 3	Task 12M		
PROCESSID 7878 Review possible legal / regulator changes that might affect Viamed / VST	Audit : Task: 807 344596x Managing Director  Audit : Terms	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 layout, can be done manually	Audit : Task: 42 315552 ✓ Managing Director  Audit :1070 Company Secretary 319066 ✓	Freq 2 Risk 1 Overall 2	Task 12M Audit 12M		
PROCESSID 7895 To conitune our FDA registration (for the Apgar timer)	Audit : Task: 825 Managing Director 345614 ✓	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	Audit : Task: 1094 Managing Director 345110 x Audit : in terms	Freq 1 Risk 1 Overall 1	Task 12M		
Director 1 (Derek)					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 8018	Task: 1193 346561 ✓	Freq 1	Meeting		



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Rolling Issue for Notes During the Weekly Meeting To discuss any problems, to assess work load and staffing. To review issues.	Managing Director Audit :	Risk 1 Overall 1	1W		
ISO Controller					
<b>Process Scope</b>	<b>Roll Task</b> <b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>
PROCESSID 29 Annual license check,  ensure no changes to Products licenced through CMDCAS,  and Issue CMDCAS a statement that No changes have occurred. NO LONGER KEEP THIS CERTIFICATE Certificate will go out of date 1st November,  Check Canadian Gazette for Latest Version of the MDR	Task: 49 340942 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 Managing Director Audit : 346231 ✓	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 future	Task: 748 Managing Director Audit : 342081 ✓	Freq 1 Risk 1 Overall 1	Task 12M		
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 Managing Director Audit : 342290 ✓	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 342445 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 344828 Managing Director * in terms Audit : 819 345614 ✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M		
PROCESSID 7895 To conitune our FDA registration	Task: 825 337146 Managing Director ✓	Freq 1 Risk 1	Task 12M		



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(for the Apgar timer)	Audit :	Overall 1			
<b>PROCESSID 7977</b> 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 337146 ✓ Company Secretary Audit : 1101 342309 ✓ Managing Director	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M		
<b>PROCESSID 7978</b> 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 Managing Director Audit : 345055 ✓ in terms	Freq 1 Risk 3 Overall 3	Task 12M		
<b>PROCESSID 7979</b> 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 336469 ✓ Managing Director Audit :	Freq 1 Risk 2 Overall 2	Task 12M		
<b>PROCESSID 7980</b> 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  <a href="http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm">http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm</a>	Task: 1103 Managing Director Audit : 312597 ✓	Freq 1 Risk 2 Overall 2	Task 12M		
<b>PROCESSID 7981</b> To review monthly any changes, to any processes, for risks to ISO systems.	Task: 1104 344603 ✓ Managing Director in terms Audit : 1105 345632 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M		
<b>PROCESSID 8036</b> To review any new rolling future issues check they have a processed it is linked to. Make sure it not duplicated	Task: 1234 332955 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 6M		
<b>IT Controller</b>					
<b>Process Scope</b>	<b>Roll Task Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>
<b>PROCESSID 6813</b> Ensure the turnover report is accurate	Task: 459 346757 ✓ Managing Director Audit : 460 331373 ✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M		
<b>PROCESSID 7918</b>	Task: 923	Freq 1			



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To backup Jeans files NO LONGER REQUIRED JEAN DOES NOT HAVE FOLDER ANYMORE	Audit :	Risk 1 Overall 1			
<b>Sales Controller</b>					
<b>Process Scope</b>	<b>Roll Task Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>
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 339674 ✓ Director 3 (Steve)  Audit :	Freq 1 Risk 1 Overall 1	Task 3M		
PROCESSID 8073 Quarterly Stock Meeting Due - Full Stock Meeting Due	Task: 82 342405 ✓ Managing Director  Audit :	Freq 1 Risk 1 Overall 1	Task 3M		
<b>Warehouse Team Leader</b>					
<b>Process Scope</b>	<b>Roll Task Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>
PROCESSID 7753 To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse.	Task: 589 344584 Managing Director in terms Audit :590 345322 ✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M		
<b>UK Sales Controller</b>					
<b>Process Scope</b>	<b>Roll Task Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>
PROCESSID 8026 To review competitor automotive prices	Task: 1210 343949 ✓ Marketing Processes  Audit :	Freq 1 Risk 1 Overall 1	Task 1M		
<b>Human Resources</b>					
<b>Process Scope</b>	<b>Roll Task Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>
PROCESSID 7964 To check the Roles and tasks tables for any gaps /red crosses Fill in the missing information where needed.	Task: 1065 345333 ✓ Company Secretary  Audit :1066 333828 ✓ 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	Task: 1208 323226 ✓ Company Secretary  Audit :1209 327649 ✓	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M		



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<p>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.'</p> <p>With this in mind we have reasoned we are not required to appoint any EU European representatives in EU member states.</p>		Managing Director					
<b>Data Protection Officer</b>							
<b>Process Scope</b>	<b>Roll Task</b> <b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>		
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 343233 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 343942x Company Secretary Audit : in forms	Freq 1 Risk 1 Overall 1	Task 3M				
<b>Audits</b>							
<b>Process Scope</b>	<b>Roll Task</b> <b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>		
PROCESSID 7886 To carry out Audit 18 Management Review Viamed	Task: 344045x Audit : 21 in forms Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M				
PROCESSID 7887 To carry out Audit 18 Management Review VST	Task: 343909x Audit : 188 in forms Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M				
<b>Office Processes</b>							
<b>Process Scope</b>	<b>Roll Task</b> <b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>*</b>	<b>Notes</b>		
PROCESSID 7750 Meeting between management and office team leader to discuss improvement of systems and address any issues	Task: 275 346506x Managing Director in forms 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					



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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)