Internal Audit Check list			
INTERNAL PROCESS VERIFICATION			
Created:	17/May 1995	**Audit No 20** **Sit With management and Complete this Form**	
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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.1.1	**General** Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	
VST Ltd ISO9001:2015 5.2.1	**Establishing the quality policy** Top management shall establish, implement and maintain a quality policy that: 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.	
VST Ltd		

ISO9001:2015 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.	
VST Ltd ISO9001:2015 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.	
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 quality management system c) controlled in accordance with the requirements of this International	

	Standard and applicable regulatory requirements.	
Viamed Ltd ISO13485:2016 4.2.1 General	**Documentation requirements** The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	
Viamed Ltd ISO13485:2016 4.2.2 Quality manual	**Documentation requirements** The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	
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.	
Viamed Ltd ISO13485:2016 5.4.1	**Quality objectives** Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and	

	consistent with the quality policy.	
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. Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.	
Viamed Ltd ISO13485:2016 5.5.2	**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 ISO13485:2016 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.	
Viamed Ltd ISO13485:2016 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 ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. 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.	
Viamed Ltd ISO13485:2016 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. Records of rework shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016 8.5.3	**Preventive action** 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. The organization shall document a procedure to describe requirements for: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; 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; e) reviewing the effectiveness of the preventive action taken, as appropriate. Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).	

	INTERNAL PROCESS VERIFICATION 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		
	<u>A - MANAGEMENT SYSTEM</u>		
	Is the Quality Statement Policy and Objectives reviewed annually. ISO – Document Index Task ID (300). Search Issues and review.		
	Is the process manual up to date. ISO – Document Index Task ID (548). Search Issues and review.		

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	Is documentation checked prior to formal approval and issue		
	Check that there is a system in operation for the request for amendments.		
	Verify that amendments are updated electronically and old copies archived.		
	Are sales orientated records filed and archived correctly in the ORD files, in the office and archiving.		
	Has organisation Chart changed. VM3COP02.02		
	Has personnel responsibility descriptions changed. Roles Titles Processes and Procedures ADMIN Over View for complete list		
	Check that the CE files are maintained by sole responsibility.		
	Check that the Notified body is informed of major changes to Documentation.		
	Check that electronic documents are regularly backed up and secure off site. ISO – Document Index Task ID (452). Search Issues and review.		

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1	Is the management system applications a series of process controls and are they in place throughout the organisation. Are processes identified and are charts produced to this effect and are copies of these charts easily accessible for use by personnel.	Intrastats, Audit 10	
2	Check the documented system for its policies and objectives and its control of the above processes and procedures. Is the Process Manual up to date and does it indicates the company's objectives. Are procedures are in place Are they available to all personnel Are other company documents i.e. Technical Drawings, Standards; Operators Manuals etc. also available and controlled	Intrastats, Audit 10 Roles and Responsibilities.	
3	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	
4	Is the Managing Director or designate manager still giving final approval for document changes.		
5	Has the Business Continuity Plan has expired. ISO – Document Index Task 266		
	B - MANAGEMENT RESPONSIBILITY		
6	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	
7	Are all customer requirements defined and met.	Contract Review Audit 2	
8	Are all the processes and objectives, undertaken within the company, documented in intrastats and have a procedure. Is it measurable. Check process for measurable ID114 Documented In Staff – Audit of Roles, titles and procedures.		
9	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	
10	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	Issues, Message of Day, company meetings, management meetings, Management weekly reviews	

11	Are all required actions are undertaken in a timely ,manner and closed where appropriate.	Intrastat Issues	
12	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)		
13	Are actions recorded against verifications completed in a timely and responsible manner.	Intrastat Issues	
14	Are design changes recorded and all the relevant information filed in the appropriate places.	Design control Audit 3 Intrastat	
	C - RESOURCE MANAGEMENT		
15	Has top management established a mechanism for identifying and providing required resources, training etc.	Training Audit 8	
16	Does this include existing and new personnel.	Training Audit 8	
17	Has top management identified the competency levels and attributes required for existing and new personnel.	Training Audit 8	
18	Is the competency of personnel monitored, verified and the appropriate records maintained	Training Audit 8	
19	Are personnel responsibilities defined.	Roles and Responsibilities	
20	Do individuals know their responsibilities, reporting and communicating lines. Each employee has 'My Roles' Link Task 314	Intrastat communication	.
21	Verify that all procedures, detail who is responsible for it.		
22	Check that these responsibilities also cover personnel Health & Safety functions – Health and Safety Controller.		
23	Is the need for equipment, plant, services etc. identified and acted upon where necessary.	Production meetings, management meetings Health and Safety Questionnaire.	
24	Has the basic working infrastructure been planned with conformity to requirements in mind.	Health & safety Audit 19	
25	Check validations of unknown process control criteria. Are there any unknown process.		

26	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	COP/07	
27	Are the controls in place, to safeguard customer property, adequate for full protection against loss damage etc.	COP/09	
28	Is the process for monitoring and measurement of product in place at all stages throughout the production process.	Production COPs	
29	Is the process for control of measuring equipment adequate for the monitoring of product verifications.	Calibration Audit 06	
30	Are validity processes are in place to safeguard product integrity.	Bar coding traceability	
	D - PRODUCT REALISATION		
31	Is the planning process for the realisation of product undertaken at the relevant stages.		
32	Does planning identify documentation, testing and other such activities as required and that all appropriate records are maintained.		
33	Are all customer requirements being addressed, including statutory and regulatory and that the capabilities are identified to meet those requirements.	Contract Review Audit 02	
34	Establish that mechanisms are in place to review all customer requirements prior to any commitments by the organisation.	Contract Review Audit 02	
35	Check that there are adequate arrangements for customer communications and feedback.	Contract Review Audit 02	
36	Is collation and analysis of all relevant data determined and effective. Is corrective actions identified.		
37	Are these actions completed in a timely and adequate manner and are these actions part of continual improvements.		
38	Does the organisation have preventive measures in place to control potential non-conformities.		
39	Are all the above actions are reviewed adequately.		
	E - DESIGN & DEVELOPMENT		
40	Are procedures in place to ensure adequate planning of product design and that all relevant stages are identified.	Design control Audit 3	
41	Are the interfaces and assignments of responsibilities identified.	Design control Audit 3	
42	Are all input requirements determined. Is the documentation identified.	Design control Audit 3	
43	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	
45	Are actions recorded against verifications completed in a timely and responsible manner.	Design control Audit 3	

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46	Are validation processes in place and are they determined in accordance with the relevant requirements.	Design control Audit 3	
47	Are design changes recorded and all the relevant information filed in the appropriate places.	Design control Audit 3	
	F - PRODUCT PROVISION		
48	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	
49	Is all the required information necessary, forwarded to suppliers in the correct format. Is this authorised prior to order placement.	Purchasing Controls (Supplier Performance) Audit 5	
50	Are goods and services received correct to the requirements stipulated.	Goods Inward Audit 9	
51	Are the provisions available, suitable for control of production and service, including procedures and equipment etc.	Production Audit 15	
52	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	Production Audit 15	
53	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Production Audit 15	
54	Is the process for monitoring and measurement of products in place at all stages throughout the production process.	Production Audit 15	
5	Is the process, for control of measuring equipment, adequate for the monitoring of product verifications.	Calibration Audit 6	
56	Are validity processes are in place to safeguard product integrity.		
	G - PROCESS MONITORING		
57	Are mechanisms are in place to monitor all relevant processes, including customer satisfaction. Are these verified against known criteria. Check process ID 114		
58	Are controls in place for non-conforming product and processes. Are adequate to prevent unintended uses.	Goods Inward Audit 9	
59	Where non-conforming product / process has been detected is appropriate action taken.	Goods Inward Audit 9	
60	Is collation and analysis of all relevant data determined and effective Is corrective actions identified.		
61	Are these actions completed in a timely and adequate manner. Are these actions part of continual improvements.		
62	Does the organisation have preventive measures in place to control potential non-conformities.	Goods Inward Audit 9	
63	Are all the above actions are reviewed adequately. Check process ID 114	Annually	

64	Are regular analyses undertaken to identify any outstanding requirements.	Intrastats	
65	Are necessary changes implemented where and when required.		
66	Is any outsourcing done.		
67	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	
68	Are records of inspections filed.	Audits	

Sub Processes Linked to Audit

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

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7730** To carry out Audit 20 Process Verification To Management Viamed		172 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7778** To carry out Audit 20 Process Verification To Management VST		181 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	