Internal Audit Check list			
CORRECTIVE ACTIONS			
Created:	17/May 1995	**Audit No 14**	
Revised:	24 October 2017		Page 1 of 10
Audit Date		Auditor	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 10.1	**General** The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include: a) improving products and services to meet requirements as well as to address future needs and expectations; b) correcting, preventing or reducing undesired effects; c) improving the performance and effectiveness of the quality management system. NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.	
VST Ltd ISO9001:2015 10.2.1	When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	
VST Ltd ISO9001:2015 8.5.5	**Post-delivery activities** The organization shall meet requirements for post-delivery activities associated with the products	

	and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	
VST Ltd ISO9001:2015 9.1.2	**Customer satisfaction** The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.	
Viamed Ltd ISO13485:2016 5.6.2 Review input	**General** The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.	
Viamed Ltd ISO13485:2016 7.2.3	**Communication** The organization shall plan and document arrangements for communicating with customers in relation to: a) product information; b) enquiries, contracts or order handling, including amendments; c) customer feedback, including complaints; d) advisory notices. The organization shall communicate with regulatory authorities	

	in accordance with applicable regulatory requirements.	
Viamed Ltd ISO13485: 2016 7.5.4	**Servicing activities** If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485: 2016 8.1	**General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to: a) demonstrate conformity of product; b) ensure conformity of the quality management system; c) maintain the effectiveness of the quality management system. This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.	
Viamed Ltd ISO13485: 2016 8.2.1	**Feedback** As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented. The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.	
Viamed Ltd ISO13485: 2016 8.2.2	**Complaint handling** The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.	

	These procedures shall include at a minimum requirements and responsibilities for: a) receiving and recording information; b) evaluating information to determine if the feedback constitutes a complaint; c) investigating complaints; d) determining the need to report the information to the appropriate regulatory authorities; e) handling of complaint-related product; f) determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Complaint handling records shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485: 2016 8.2.3	**Reporting to regulatory authorities** If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.5).	
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 8.3.2	**Actions in response to nonconforming product detected before delivery** The organization shall deal with nonconforming product by one or more of the following ways: a) taking action to eliminate the detected nonconformity; b) taking action to preclude its original intended use or application; c) authorizing its use, release or acceptance under concession. The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485: 2016 8.3.3	**Actions in response to nonconforming product detected after delivery** When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5). The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485: 2016 8.4	**Analysis of data** The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from	

	other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485: 2016 8.5.1	**General** The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.	
Viamed Ltd ISO13485: 2016 8.5.2	**Corrective action** The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; f) reviewing the effectiveness of corrective action taken Records of the results of any investigation and action taken 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).	

QUESTION:	**RESPONSE:**	**Y/N**
Verify that all are reviewed regularly. This can be done by checking the management meeting minutes, issues.& actions		
Check that customer complaints & non-conformities are reviewed regularly at management meetings	Intrastats	
Check that these reviews assess the cause of the non-conformities.	Intrastats	
Verify that action is taken to ensure that stated non-conformities do not recur.		
Verify that records of these actions are retained.	Intrastats	
Check that corrective actions taken are reviewed.	Intrastats	
Check that reviews are undertaken to assess potential cause of non-conformities.	Intrastats	
Verify that the need for action to prevent these occurrences is evaluated.		
Check that any action deemed necessary has been undertaken and records retained.		
Check that preventive action taken is reviewed.		
Check that the appropriate authority undertakes regular update reviews.i.e management meeting minutes		
Verify that reviews are presented to the annual management review.		
Are Customer complaints properly recorded Hard copy & Intrasasts		
Is the complaint Index completed correctly Hard copy		

Is the complaint Report completed correctly Hard copy		
Are reports/correspondence filed in the customer file		
Has corrective action been taken and recorded		

Sub Processes Linked to Audit 14

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

Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **6931** Review the Customer Complaints Heading	728 Managing Director	774 Company Secretary	Freq 4 Risk 1 Overall 4	Task 1W Audit 6M	
PROCESSID **7838** Review Customer Feedback Negative	739 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7839** To Review Viamed Customer Complaints	737 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7840** To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	740 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7841** To review Customer Complaints see if Non Conformance need to be raised	738 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7842** To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	741 Managing Director		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7843** To review Negative	742 Managing		Freq 3 Risk 1	Task 1M	

feedback form Products see if Non Conformance or customer Complaints need to be raise	Director		Overall 3		
PROCESSID **7849** Review the Customer Returns and Review Product Failures New Codes	750 Managing Director	751 Director 3 (Steve)	Freq 4 Risk 3 Overall 12	Task 1W Audit 3M	

ISO Controller

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **6828** To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement.	88 Company Secretary	284 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	
PROCESSID **7199** To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement.	88 Company Secretary	284 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	
PROCESSID **7743** Major Customer Complaints get escalated to Paper Customer Complaints file. Check the File is being Maintained and any relevant documentation is in the File.	75 Managing Director		Freq 2 Risk 1 Overall 2	Task 6M	

Humanmed Controller

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7671** Humanmed Non	747 Managing		Freq 3 Risk 2	Task 1M	

Conformances	Director	Overall 6

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7726** To carry out Audit 14 Complaints And Corrective Actions Viamed		30 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7774** To carry out Audit 14 Complaints And Corrective Actions VST		189 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	