Viamed + VST

Internal Audit Check list

CORRECTIVE ACTIONS

Created:	17/May 1995	**Audit No 14**	
Revised:	22 November 2019		Page 1 of 14
Audit Date	22-11-19	Auditor Helen Lamb	

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.	Interlab feedback Issues VOPs
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:	Issues + VOP

	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.	Issues + management meetings
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.	Ultrastate feed back issues Returns section Ultrastate
VST Ltd ISO9001:2	**Customer satisfaction** The organization shall monitor customers' perceptions of the degree to which their needs	feed back.

015 9.1.2	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.	feedback + cust complaints Intrastats
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.	GDPR SOP + feedback Intrastats.
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).	Vaps Intrastats Doc index Service log. issues Repairs Section Intrastats
Viamed Ltd	**Feedback** As one of the measurements of the effectiveness of the quality management system, the organization	non conformance Review

ISO13485: 2016 8.2.1	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.	feedback Intastats
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).	VOP Issues Intastats Doc index Management Review
Viamed Ltd	**Reporting to regulatory authorities** If applicable regulatory requirements require notification of complaints that meet specified reporting	

ISO13485: 2016 8.2.3	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).	VOP
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).	VOP Viastat b Doc index QA Records
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).	VCP Route Map management Review Issues Viastat b
Viamed	**Preventive action**	

Ltd ISO13485: 2016 8.5.3	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).	Issues non conformace Review.

QUESTION:	**RESPONSE:**	**Y/N**
Verify that all are reviewed regularly. This can be done by checking the management meeting minutes, issues.& actions	Task lol. 728 160620 ✓	Y
Check that customer complaints & non-conformities are reviewed regularly at management meetings	Intrastats	Y
Check that these reviews assess the cause of the non-conformities.	Intrastats NO Non Conformaties	N/A
Verify that action is taken to ensure that stated non-conformities do not recur.		N/A

Verify that records of these actions are retained.	Intrastats	Y
Check that corrective actions taken are reviewed.	Intrastats Tash Id 88 160101x in terms 137398 ✓	Y
Check that reviews are undertaken to assess potential cause of non-conformities.	Intrastats Tash id 284	Y
Verify that the need for action to prevent these occurrences is evaluated.	non Conformace Review	Y
Check that any action deemed necessary has been undertaken and records retained.		Y
Check that preventive action taken is reviewed.	Issues Reviewed on Completion	Y
Check that the appropriate authority undertakes regular update reviews .ie. management meeting minutes	Board Meeting Annual	Y
Verify that reviews are presented to the annual management review.		Y
Are Customer complaints properly recorded Hard copy & Intrastasts		Y
Is the complaint Index completed correctly Hard copy		Y
Is the complaint Report completed correctly Hard copy		Y
Are reports/correspondence filed in the customer file	No Customer file. Needs Reviewing	N/A
Has corrective action been taken and recorded		Y

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	Brief Description	Responsibility/ Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
				#159223 ✓ #157853					
6931 - *History/Details* Review the Customer Complaints Heading	Customer Complaints	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd 24129 VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd	ISO - ISO Review - Non Conformance / Customer Complaints Review Are all those listed reviewed. Do they have ticks where necessary, tasks, issues and completion notes added. Check the previous months. #159166	728 Managing Director	774 Company Secretary	4	1	4	Task 1W Audit 6M
7838 - *History/Details*	Review VIAMED	24125 VOP 19 FeedBack Customer	Go to the meeting heading Customer	739 ✓ Managing		3	1	3	Task 1M

Review Customer Feedback Negative	Feedback - Customer Feedback Negative	Complaints Vigilance and Notifications Viamed Ltd	Feedback Negative and review the last 3 months, or since last review	Director #159141 ✓				
7839 - ***History/Details*** To Review Viamed Customer Complaints	Review VIAMED Feedback - Customer Complaints	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd	Go to the meeting heading Customer Complaints and review the last 3 months, or since last review	737 Managing Director	3	1	3	Task 1M
7840 - ***History/Details*** To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	Review VST Feedback - Customer Feedback Negative	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd	Go to the meeting heading Customer Feedback Negative and review the last 3 months, or since last review	740 #159144 Managing Director	3	1	3	Task 1M
7841 - ***History/Details*** To review Customer Complaints see if Non Conformance need to be raised	Review VST Feedback - Customer Complaints	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd	Go to the meeting heading Customer Complaints and review the last 3 months, or since last review #159162	738 Managing Director	3	1	3	Task 1M

#159145

7842 ***- History/Details*** To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	Review VIAMED Product Feedback Negative	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd	Go to the meeting heading Product Feedback Negative and review the last 3 months, or since last review	741 Managing Director	3	1	3	Task 1M

#159146

7843 ***- History/Details*** To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise	Review VST Product Feedback Negative	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd	Go to the meeting heading Product Feedback Negative and review the last 3 months, or since last review	742 Managing Director	3	1	3	Task 1M

#159607 #157850 + terms

7849 ***- History/Details*** Review the Customer Returns and Review Product Failures New Codes	Review Product Failures New Codes	24121 VOP 10 Non Conformance, Corrective and Preventive Actions		750 Managing Director	751 Director 3 (Steve)	4	3	12	Task 1W Audit 3M

Humanmed Controller

Process Scope	Brief Description	Responsibility/ Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7671 - *History/Details* Humanmed Non Conformances	Humanmed Non Conformances	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd		#159140 ✓ 747 Managing Director		3	2	6	Task 1M

ISO Controller

Process Scope	Brief Description	Responsibility/ Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
6865	Non Conformance Effectiveness	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data							
7199 ***- History/Details***	Non Conformities	24121 VOP 10 Non Conformance,	look at the past non conformance review	#158168 ✓ #137398 88 Company	284 Managing	3	1	3	Task 1M

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.	Review	Corrective and Preventive Actions	and make sure it has been issued within three months	Secretary	Director				Audit 12M
7743 ***- History/Details*** Major Customer Complaints get escalated to Paper Customer Complaints file. Check the File is being Maintained and any relevant documentation is in the File.	Customer Complaints Paper File	24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd 24129 VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd 6098 QC 11 Customer	#155100	75 Managing Director	2	1	2		Task 6M

Complaints Index
6096 QC 12
Customer
Complaints Report
form QC12
8700 Chart 27
Customer
Complaints Chart 27

Audits

Process Scope	Brief Description	Responsibility/ Procedure/ Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7726 - ***History/Details*** To carry out Audit 14 Complaints And Corrective Actions Viamed	Audit 14 Complaints And Corrective Actions Viamed	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			#158599 x 1n terms 30 Company Secretary	2	2		Audit 12M
7774 - ***History/Details*** To carry out Audit 14 Complaints And Corrective Actions VST	Audit 14 Complaints And Corrective Actions VST	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			#158604 x items 189 Company Secretary	1	2	2	Audit 12M