

Internal Audit Check list

VIAMED LTD CORRECTIVE ACTIONS

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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485: 2016 7.2.3	<p>Communication</p> <p>The organization shall plan and document arrangements for communicating with customers in relation to:</p> <ul style="list-style-type: none"> a) product information; b) enquiries, contracts or order handling, including amendments; c) customer feedback, including complaints; d) advisory notices. <p>The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.</p>	<p>Doc inlex</p> <p>Roles + Processes</p> <p>Route maps</p>
Viamed Ltd ISO13485: 2016 7.5.4	<p>Servicing activities</p> <p>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.</p> <p>The organization shall analyse records of servicing activities carried out by the organization or its supplier:</p> <ul style="list-style-type: none"> a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. <p>Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).</p>	<p>Doc inlex</p> <p>Tech files</p> <p>QA System</p>
Viamed Ltd ISO13485: 2016 8.2.1	<p>Feedback</p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>Roles + files</p> <p>Doc inlex</p> <p>management review</p>

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	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	<p>Complaint handling</p> <p>The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.</p> <p>These procedures shall include at a minimum requirements and responsibilities for:</p> <ul style="list-style-type: none"> 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. <p>If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.</p> <p>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.</p> <p>Complaint handling records shall be maintained (see 4.2.5).</p>	<p>Roles + Gates Doc index management Review Route map</p>
Viamed Ltd ISO13485: 2016 8.2.3	<p>Reporting to regulatory authorities</p> <p>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.</p> <p>Records of reporting to regulatory authorities shall be maintained (see 4.2.5).</p>	<p>Procedure Doc index Route map</p>
Viamed Ltd ISO13485: 2016 8.3.3	<p>Actions in response to nonconforming product detected after delivery</p> <p>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).</p> <p>The organization shall document procedures for issuing</p>	<p>Doc index procedures</p>

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	<p>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).</p>	
Viamed Ltd ISO13485: 2016 8.5.2	<p>Corrective action</p> <p>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.</p> <p>Corrective actions shall be proportionate to the effects of the nonconformities encountered.</p> <p>The organization shall document a procedure to define requirements for:</p> <ul style="list-style-type: none"> 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 <p>Records of the results of any investigation and action taken shall be maintained (see 4.2.5).</p>	<p>Management Review</p> <p>Doc index</p>
Viamed Ltd ISO13485: 2016 8.5.3	<p>Preventive action</p> <p>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.</p> <p>The organization shall document a procedure to describe requirements for:</p> <ul style="list-style-type: none"> 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. 	<p>Doc index</p> <p>Procedure</p> <p>Review meetings</p>

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Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

Planned.

	QUESTION:	RESPONSE:	Y/ N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
2	Verify that all are reviewed regularly. This can be done by checking the management meeting minutes, issues.& actions. Task ID 728. All renewed in management review.	3416545 ✓	Y
3	Check that customer complaints & non-conformities are reviewed regularly at management meetings	Intrastats	Y
4	Check that these reviews assess the cause of the non-conformities.	Intrastats	Y
5	Verify that action is taken to ensure that stated non-conformities do not recur.		Y
6	Verify that records of these actions are retained.	Intrastats	Y
7	Check that corrective actions taken are reviewed. Task ID 283 and 285. 3415967 ✓ 345968 ✓	Intrastats	Y
8	Check that reviews are undertaken to assess potential cause of non-conformities. Task ID 284.	319655 ✓	Y
9	Verify that the need for action to prevent these occurrences is evaluated.	QC 21 form	Y
10	Check that any action deemed necessary has been undertaken and records retained.		Y
11	Check that preventive action taken is reviewed.	QC 21 completion Section	Y

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12	Check that the appropriate authority undertakes regular update reviews. i.e. management meeting minutes.	Renewed minutes	Y
13	Verify that reviews are presented to the annual management review.	Renewed minutes	Y
14	Are Customer complaints properly recorded Hard copy & Instrastats.		Y
15	Is the complaint Index completed correctly Hard copy.		Y
16	Is the complaint Report completed correctly Hard copy.		Y
17	Has corrective action been taken and recorded	file + issues.	Y

Sub Processes Linked to Audit 14

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

List Processes Per Title

Clone from Docid

Managing Director		Roll Task	Risk	Action	*	Notes
Process Scope	Roll Audit					
PROCESSID 6931 Review the Customer Complaints Heading	Task: 728 Managing Director	Freq 1 Risk 3 Overall		Task 1W Audit 6M		

346545

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	Audit :774 Company Secretary	3 34561✓			
PROCESSID 7838 Review Customer Feedback Negative	Task: 739 Managing Director 364591✓	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID 7839 To Review Viamed Customer Complaints	Task: 737 Managing Director 364589✓	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	Task: 740 Managing Director 364592✓	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID 7841 To review Customer Complaints see if Non Conformance need to be raised	Task: 738 Managing Director 364590✓	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	Task: 741 Managing Director 364593✓	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID 7843 To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise	Task: 742 Managing Director 364594✓	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID 7849 Review the Customer Returns and Review Product Failures New Codes	Task: 750 Managing Director 366376✓	Freq 1 Risk 3 Overall 3	Task 1W Audit 3M		

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	Audit :751 Director 3 (Steve)	345608 ✓				
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ISO Controller

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
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.	Task: 283 Company Secretary 345967 ✓ Audit :284 Managing Director 319655 ✓	Freq 2 Risk 2 Overall 4	Other 1M Audit 12M		
PROCESSID 7264 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.	Task: 285 Company Secretary 345968 ✓ Audit :286 Managing Director	Freq 3 Risk 2 Overall 6	Task 1M Task 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.	Task: 75 Managing Director 34930 ✓ Audit :	Freq 2 Risk 1 Overall 2	Task 6M		

IT Controller

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7934 Test the integration of the	Task: 973	Freq 1 Risk 1			

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website submitted questions to intrastats	Audit: 1176	Overall 1				
TASK NO LONGER REQUIRED, SHOPIFY EMAILS QUESTIONS						
Humanmed Controller						
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes	
PROCESSID 7671 Humanmed Non Conformances	Task: 747 Audit :	Freq 2 Risk 2 Overall 4				
OEM Sales Controller						
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes	
PROCESSID 7965 Enter Feedback from VST customer or Suppliers in the the Feedback headers Both Positive and Negative feedback to be logged	Task: 1068 Director 3 (Steve) 345334 ✓ Audit :1069 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 12M			
Audits	325535 ✓					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes	
PROCESSID 7726 To carry out Audit 14 Complaints And Corrective Actions Viamed	Task: 346833 Audit :30 Company Secretary	Freq 1 Risk 2 Overall 2 in terms	Audit 12M			
PROCESSID 7774 To carry out Audit 14 Complaints And Corrective Actions VST	Task: 346837 Audit :189 Company	Freq 1 Risk 2 Overall 2 in terms	Audit 12M			

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Secretary

Rolling Tasks Linked to Document :Task (30) Task (189) Task (75) Task (283) Task (747) Task (739) Task (737) Task (740) Task (738) Task (741) Task (742) Task (750) Task (728) Task (973) Task (1068) Task (285)