Internal Audit Check list			
VIAMED LTD CORRECTIVE ACTIONS			
Created:	17/May 1995	**Audit No 14**	
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Audit Date	25-11-25	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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.	Roles + tasks Route map Doc index
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).	Doc index Tech files QA systems procedures
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	Roles + tasks Doc index management Review procedures

	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).	Roles + tasks Doc index Route map Management Review
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).	Procedures Doc index Route map.
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	Issues Procedures Doc index

	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 8.5.2	**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).	management Reviews Issues
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	management Review Doc index Issues.

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	shall be maintained (see 4.2.5).	

	QUESTION:	**RESPONSE:**	**Y/ N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory. Nothing outstanding	No problems	Y
2	Verify that all are reviewed regularly. This can be done by checking the management meeting minutes, issues.& actions. Task ID 728. 381561	all upto date	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. 380043 ✓ 380064 ✓	Intrastats	Y
8	Check that reviews are undertaken to assess potential cause of non-conformities. Task ID 284. 354695 ✓	Intrastats	Y
9	Verify that the need for action to prevent these occurrences is evaluated.		Y
10	Check that any action deemed necessary has been undertaken and records retained.		Y
11	Check that preventive action taken is reviewed.		Y

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12	Check that the appropriate authority undertakes regular update reviews. i.e. management meeting minutes.		Y
13	Verify that reviews are presented to the annual management review.		Y
14	Are Customer complaints properly recorded Hard copy & Intrastats.		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		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

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Managing Director				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*Notes
PROCESSID **6931** Review the Customer Complaints Heading	Task: 728 381561 Managing Director Audit :774 379683	Freq 1 Risk 3 Overall 3	Task 1W Audit 6M	

	Company Secretary				
PROCESSID **7838** Review Customer Feedback Negative	Task: 739 381564 ✓ Managing Director Audit :	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID **7839** To Review Viamed Customer Complaints	Task: 737 381562 ✓ Managing Director Audit :	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 381565 ✓ Managing Director Audit :	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID **7841** To review Customer Complaints see if Non Conformance need to be raised	Task: 738 381563 ✓ Managing Director Audit :	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 381566 ✓ Managing Director Audit :	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 381567 ✓ Managing Director Audit :	Freq 3 Risk 1 Overall 3	Task 1M		
PROCESSID **7849** Review the Customer Returns and Review Product Failures New Codes	Task: 750 381434 ✓ Managing Director Audit :751 379680 ✓ Director 3 (Steve)	Freq 1 Risk 3 Overall 3	Task 1W Audit 3M		
ISO and Compliance Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*Notes	
PROCESSID **7199** To review any non conformances	Task: 283 380043 ✓ Company Secretary	Freq 2 Risk 2	Other 1M		

created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement.	Audit :284 3544957 Managing Director	Overall 4	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 3800444 Company Secretary Audit :286 3544967 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 3766214 Managing Director Audit :	Freq 2 Risk 1 Overall 2	Task 6M		
PROCESSID **8089** Review Any Outstanding QC 21 Forms. If completed, sign it off. Review it to make sure all parts are completed satisfactorily	Task: 1276 3803037 Managing Director Audit :1277 3675377 Company Secretary	Freq 1 Risk 3 Overall 3	Task 1M Audit 12M		
IT Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**		*Notes
PROCESSID **7934** Test the integration of the website submitted questions to intrastats TASK NO LONGER REQUIRED, SHOPIFY EMAILS QUESTIONS	Task: 973 Audit :1176	Freq 1 Risk 1 Overall 1			

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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 371208 × Director 3 (Steve) out of terms Audit :1069 Managing Director 360659 ✓	Freq 2 Risk 2 Overall 4	Task 3M Audit 12M	

Issue 381760 Sent possibly Non Con. DL to Roman

Audits

Process Scope	Roll Task Roll Audit	Risk	Action	*Notes
PROCESSID **7726** To carry out Audit 14 Complaints And Corrective Actions Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :30 380037 × Company Secretary Audit	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7774** To carry out Audit 14 Complaints And Corrective Actions VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.	Task: 380842 Audit :189 × Company Secretary Audit	Freq 1 Risk 2 Overall 2	Audit 12M	

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If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.					

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) Task (1276)