Internal Audit Check list
Viamed Returns, Repairs & Service Audit

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Revised:	15 July 2024		Page 1 of 5
Audit Date	19-7-24	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 7.2.2	**Review of requirements related to product** The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: a) product requirements are defined and documented; b) contract or order requirements differing from those previously expressed are resolved; c) applicable regulatory requirements are met; d) any user training identified in accordance with 7.2.1 is available or planned to be available; e) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	management Review Doc index Route map Training Records
Viamed Ltd ISO13485:2016 7.5.10	**Customer property** The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).	Doc index Barcodes procedures
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 system Procedures

Viamed Ltd ISO13485:2016 7.5.6	**Validation of processes for production and service provision** The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes including: a) defined criteria for review and approval of the processes; b) equipment qualification and qualification of personnel; c) use of specific methods, procedures and acceptance criteria; d) as appropriate, statistical techniques with rationale for sample sizes; e) requirements for records (see 4.2.5); f) revalidation, including criteria for revalidation; g) approval of changes to the processes. The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).	*Doc index* *Bar code system* *management Review* *calibration index*
Viamed Ltd ISO13485:2016 7.5.8	**Identification** The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.	*Bar code system* *calibration index* *QA System procedures*
Viamed Ltd ISO13485:201	**Internal audit** The organization shall conduct internal audits at planned intervals	

6 8.2.4	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.	Doc Index Audit Calendar Route map Roles + titles.
Viamed Ltd ISO13485:201 6 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).	Issues Procedures QA System Doc index

	QUESTION:		RESPONSE:	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing	outstanding	Y
2	Check that out of date warranty repairs have received customer approval prior to any repair work being done.			Y
3	Verify that goods are identified as a Customer Repairs.			Y

4	Check that the QA Records – final inspection, test sheets and safety records are completed. Returns – Repairs Ready for Invoice – View Status. Copy the serial number in to serial number search in Stockbook to get the barcode ID. Paste into QA Report. All available reports will be in here.		Y
5	Check that anti-static precautions are in place and appropriate checks are recorded. Check the workshop, QA and the R+D room. Should these be in place anywhere else around the company.		Y
6	Check that the correct coloured duckets are being used for Urgent and Export repairs.		Y
7	Check that the repairs are being worked in priority, and then date order.		Y
8	Check that completed duckets are placed on the repaires shelf with all appropriate paperwork. Check all duckets on the shelves.		Y
9	Returns – Returns Completed. Pick 5 Invoiced repairs and check the paperwork in the ORD file matches the customer paperwork and the invoice. 1. SRS68839 2. SRS68837 3. SRS 68834 4. SRS 68826 5. SRS 68824		Y
10	Intrastats Service Logs – are any services overdue, list them. Intrastats – Returns – Service Visits. Look in Notes icon for further info and check any issues attached. Nothing overdue.	Stopping external Servicing.	Y
11	Intrastats Service Logs – are any services in progress. Returns – Service Visits. Check the Notes are they being filled in.		N
12	Check in the workshops and make sure all sealant, glues, greases, sprays, tapes and gases are in date and have a data sheet, if no date is present make sure there is a review to check purchase date and lifespan in Intrastats. List any without and check recurring issues for this.	Task 1011 ✓	Y
13	Returns – Repairs in building. Pick 5 from the list and go and find them, check they have the appropriate paperwork. 1. SRS 68821 2. SRS 68822 3. 4. 5. Only 2 at time of Audit		Y

14	Check the number of old repairs. Intrastats – Returns – Repairs in building. Find out what is happening with any older than 6 month. List any anomalies.	No ongoing issues	·Y
15	Returns – Ready for quote. Check the 5 oldest from the list and go and find them on the repairs shelf, check they have the appropriate paperwork. 1. 68868 2. 68858 3. 4. 5.		Y
16	Returns – Quotes sent. Check the 5 oldest to the Quotes file in the office. Are there notes on Intrastats and on the paperwork. 1. 68862 2. 68853 3. 68847 4. 5.		Y
17	Returns – Repairs Ready for Invoice. Check the oldest 5 of the Viamed SRS's. Why have they not been invoiced. 1. 68581 Internal 2. 68737 – Credited waiting completion. 3. 68768 – Internal 4. 68791 – Internal 5. 68827 – proforma waiting payment Using the same 5 copy the Barcode into the QA Report and see if they have QA records.		Y
18	Returns – Calibration Certificates. From the list click View, to go to the calibration certificate. Copy the serial number in to serial number search in Stockbook to get the barcode ID. Paste into QA Report. Check there is a QA Report is available.		Y

Sub Processes Linked to Audit 11

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

List Processes Per Title

Warehouse Team Leader

Process Scope	Roll Task Roll Audit	Risk	Action	Notes
PROCESSID **6862** The repairs that are currently in the building. Confirm the Stage and Location of repairs	Task: 614 336002 X Goods Out Audit :895 320 310 Managing Director ✓	Freq 2 Risk 1 Overall 2	Task 1W Audit 3M	
PROCESSID **7138** To review any new QC 21 Forms Check existing forms for corrective actions and effectivness	Task: 795 335487 Managing Director ✓ Audit :796 310517 Company Secretary ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	
PROCESSID **7674** Review the repairs ready For invoice List in intrastats.	Task: 468 335867 Goods Out ✓ Audit :469 Goods In 333183✓	Freq 2 Risk 1 Overall 2	Task 2W Audit 3M	
PROCESSID **7905** To arrange Supplier Returns Generate RMA box, link items and add faults	Task: 882 335911 ✓ Goods In Audit :883 330619 Office Processes ✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 3M	
PROCESSID **8052** Check Supplier returns for items not received back	Task: 272 335454 Goods Out ✓ Audit :	Freq 3 Risk 1 Overall 3	Task 1M	

Repairs Controller

Process Scope	Roll Task Roll Audit	Risk	Action	Notes
PROCESSID **7823** Backup the Fluke ESA615 Safety tester CE Copy any files to the Z Drive - safety tester backupdata	Task: 79 302841 Production Processes ✓ Audit :711 Managing Director 325678✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7993** Verification Warranty Repairs Customer Approval check the previous months non warranty repairs for customer approval prior to any work being done. Check the Repairs in History File - Completed. Search for non warranty repairs check they have customer	Task: 1131 328730 Company Secretary ✓ Audit :1171 313225 Office Processes ✓	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M	

approval. Search warranty then go down list to look for non warranty repairs have they had approval

	Task: 1132 329165 Company Secretary	Freq 1	Task 12M	
PROCESSID 7994 Verification Completed Repairs Paperwork. Check 5 Invoiced Repairs, check the paperwork Invoice matches the customer Order.	Audit :1133 312453 Managing Director	Risk 1 Overall 1	Audit 12M	
PROCESSID 7995 Verification Visual Check Repair Shelf	Task: 1134 329864 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
	Audit :1135 312599 Managing Director			
PROCESSID 7996 Verification Repairs Older Repairs Find all repairs older than 60 Days. review why not been invoice / completed.	Task: 1136 330030 Company Secretary Audit :1137 312454 Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID 7997 Verification Repair Qa Reports Find 5 Completed repairs. Check the ID has a QA record	Task: 1138 330031 Company Secretary Audit :1140 312456 Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	

Audits

Process Scope	Roll Task Roll Audit	Risk	Action	Notes
PROCESSID 7724 To carry out Audit 11 Repairs And Service Viamed	Task: This Audit 333813 x Audit :171 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7772 To carry out Audit 11 Repairs And Service VST	Task: This Audit Audit :179 333815 Company Secretary x	Freq 1 Risk 2 Overall 2	Audit 12M	

Office Processes

Process Scope	Roll Task Roll Audit	Risk	Action	Notes
PROCESSID 5857 Ensuring customer onsite service visits are completed	Task: 233 335980 x Office Processes in terms Audit :234 UK Sales Controller	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M	

336292 in terms

Process Scope	Roll Task / Roll Audit	Risk	Action	Notes	
PROCESSID **5898** Dispose of depleted oxygen sensors and send customer replacement disposal bags	Task: 406 *335983* ✓ Goods In Audit :535 *336313* ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 2W Audit 2W		
PROCESSID **7752** Ensure all outstanding repairs are being dealt with	Task: 792 *335904* ✓ Office Processes Audit :793 *329691* ✓ Office Processes	Freq 2 Risk 1 Overall 2	Task 1M Audit 3M		
PROCESSID **7760** Send letters to existing customers to remind them that a service is due on their equipment	Task: 607 *336001* ✓ Marketing Processes Audit :898 *336332* ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 1W Audit 4W		

Goods Out

Process Scope	Roll Task / Roll Audit	Risk	Action	Notes	
PROCESSID **7690** Review the Repairs completed shelf and ship those items that are ready for return to the customer.	Task: 492 *2 26303* Goods Out x in terms Audit :758 *333872* Goods In x in terms	Freq 2 Risk 1 Overall 2	Task 1D Audit 1M		
PROCESSID **7748** Check the orders against the customer paperwork, that we have generated, for the repair we have received in.	Task: 575 *336205* Goods Out x in terms Audit :1054 *325955* ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 7D Audit 12M		
PROCESSID **7749** Check the quotes that we send out for the repairs we have received in.	Task: 576 *336317* Goods Out x in terms Audit :	Freq 2 Risk 2 Overall 4	Task 1D		
PROCESSID **7906** Obtain Returns paperwork / authorisation from supplier to return Items.	Task: 884 *335912* ✓ Goods Out Audit :	Freq 1 Risk 1 Overall 1	Task 1W		

Repair Processes

Process Scope	Roll Task / Roll Audit	Risk	Action	Notes	
PROCESSID **8022** Reviewing Vandagraph Repair in Intrastats	Task: 92 *334559* ✓ EX Sales Controller Audit :91 *333812* ✓ Managing Director	Freq 1 Risk 2 Overall 2	Task 1M Task 1M		