Internal Audit Check list			
Viamed Returns, Repairs & Service Audit			
Created:	17/May 1995	**Audit No 11**	VOP 09
Revised:	16 July 2024		Page 1 of 5
Audit Date		Auditor	

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.	
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).	
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 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).	
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.	
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.	
Viamed Ltd ISO13485:2016 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).	

	QUESTION:	**RESPONSE:**	**Y/N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.		
2	Check that out of date warranty repairs have received customer approval prior to any repair work being done.		
3	Verify that goods are identified as a Customer Repairs.		

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.		
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.		
6	Check that the correct coloured duckets are being used for Urgent and Export repairs.		
7	Check that the repairs are being worked in priority, and then date order.		
8	Check that completed duckets are placed on the repaires shelf with all appropriate paperwork. Check all duckets on the shelves.		
9	Returns – Returns Completed. Pick 5 Invoiced repairs and check the paperwork in the ORD file matches the customer paperwork and the invoice. 1. 2. 3. 4. 5.		
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.		
11	Intrastats Service Logs – are any services in progress. Returns – Service Visits. Check the Notes are they being filled in.		
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.		
13	Returns – Repairs in building. Pick 5 from the list and go and find them, check they have the appropriate paperwork. 1. 2. 3. 4. 5.		

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.		
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. 2. 3. 4. 5.		
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. 2. 3. 4. 5.		
17	Returns – Repairs Ready for Invoice. Check the oldest 5 of the Viamed SRS's. Why have they not been invoiced. 1. 2. 3. 4. 5. Using the same 5 copy the Barcode into the QA Report and see if they have QA records.		
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.		

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