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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 8.2.1	**Customer communication** Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	Doc index Roles + titles Feedback procedures
VST Ltd ISO9001:2015 8.5.3	**Property belonging to customers or external providers** The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred. NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.	QA Systems Procedures Bar code tracking Doc index
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 ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals 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	**Rework**	

ISO13485:2016 8.3.4	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).	

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	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.	*Info now in SB page*	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. 134258 ✓ *Aug 22* *Very few in* 2. 133911 ✓ *list* 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. *No Services*		*N/A*
11	Intrastats Service Logs – are any services in progress. Returns – Service Visits. Check the Notes are they being filled in. *No Service*		*N/A*
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 1010 1011 1012*	*call in date*	✓
13	Returns – Repairs in building. Pick 5 from the list and go and find them, check they have the appropriate paperwork. 1. *68522* ✓ 2. *68517* ✓ 3. *68501* ✓ 4. *68500* ✓ 5. *68485* ✓		✓
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. *SRS 68279 with issue ongoing Aug 22*		✓
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. *None on List* 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. *None on List* 3. 4. 5.		✓

17	Returns – Repairs Ready for Invoice. Check the oldest 5 of the ~~Viamed and~~ VST SRS's. Why have they not been invoiced. 1. 68463 *waiting Credit with SN June 23* 2. 68471 *waiting Credit with SN June 23* 3. 4. 5. Using the same 5 copy the Barcode into the QA Report and see if they have QA records. *QA test – but ncth Data base.* *Issue # 301436 sent*		✓ ✓
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. *No calibration for VST*	*N/A*

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**	**Referenced in Document**
PROCESSID **6862** *301247* The repairs that are currently in the building. Confirm the Stage and Location of repairs *In terms*	614 Goods Out	895 Managing Director *295133*✓	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	795 Managing Director *301104*✓	796 Company Secretary *27559*✓	Freq 3 Risk 1 Overall 3		Task 1M Audit 12M	
PROCESSID **7674** Review the repairs ready For invoice List in intrastats.	468 Goods Out *300383*✓	469 Goods In *298870*✓	Freq 2 Risk 1 Overall 2		Task 2W Audit 3M	
PROCESSID **7905** To arrange Supplier Returns Generate RMA box, link items and add faults	882 Goods In *301080*✓	883 Office Processes *296382*✓	Freq 1 Risk 1 Overall 1		Task 1W Audit 3M	
Repairs Controller						
Process Scope	**Roll Task**	**Roll Audit**	**Risk**		**Action**	**Referenced in Document**

Process Scope	Roll Task	Roll Audit Risk	Action	Referenced in Document
PROCESSID **7823** Backup the Fluke ESA615 Safety tester CE Copy any files to the Z Drive - safety tester backupdata	79 Production Processes	711 Freq 1 Managing Risk 1 Director 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.	1131 Company Secretary	1171 Freq 1 Office Risk 2 Processes Overall 2	Task 12M Audit 12M	
PROCESSID **7994** Verification Completed Repairs Paperwork. Check 5 Invoiced Repairs, check the paperwork Invoice matches the customer Order.	1132 Company Secretary	1133 Freq 1 Managing Risk 1 Director Overall 1	Task 12M Audit 12M	
PROCESSID **7995** Verification Visual Check Repair Shelf	1134 Company Secretary	1135 Freq 1 Managing Risk 1 Director Overall 1	Task 12M Audit 12M	
PROCESSID **7996** Verification Repairs Older Repairs Find all repairs older than 60 Days. review why not been invoice / completed.	1136 Company Secretary	1137 Freq 1 Managing Risk 1 Director Overall 1	Task 12M Audit 12M	
PROCESSID **7997** Verification Repair Qa Reports Find 5 Completed repairs. Check the ID has a QA record	1138 Company Secretary	1140 Freq 1 Managing Risk 1 Director Overall 1	Task 12M Audit 12M	

Audits

Process Scope	Roll Task	Roll Audit Risk	Action	Referenced in Document
PROCESSID **7724** To carry out Audit 11 Repairs And Service Viamed		171 Freq 1 Company Risk 2 Secretary Overall 2	Audit 12M	
PROCESSID **7772** To carry out Audit 11 Repairs And Service VST		179 Freq 1 Company Risk 2 Secretary Overall 2	Audit 12M	

Office Processes

Process Scope	Roll Task	Roll Audit Risk	Action	Referenced in Document
PROCESSID **5857** Ensuring customer onsite service visits are completed	233 Office Processes	234 Freq 2 UK Sales Risk 1 Controller Overall 2	Task 1W Audit 1M	
PROCESSID **5898** Dispose of depleted oxygen sensors and send customer replacement disposal bags	406 Goods In	535 Freq 1 Company Risk 1 Secretary Overall 1	Task 2W Audit 2W	

PROCESSID **7752**	792	793	Freq 2	Task 1M
Ensure all outstanding repairs are being dealt with	Office Processes	Office Processes	Risk 1 Overall 2	Audit 3M
PROCESSID **7760**	607	898	Freq 1	Task 1W
Send letters to existing customers to remind them that a service is due on their equipment	Marketing Processes	Company Secretary	Risk 1 Overall 1	Audit 4W

301 245   299 375

Goods Out

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7690**	492	758	Freq 2	Task 1D	
Review the Repairs completed shelf and ship those items that are ready for return to the customer. _In terms_	Goods Out 301343 x	Goods In 29564	Risk 1 Overall 2 _In terms_	Audit 1M	
PROCESSID **7748**	575	1054	Freq 2	Task 7D	
Check the orders against the customer paperwork, that we have generated, for the repair we have received in. _in terms_	Goods Out 300843 x	Managing Director 291743	Risk 2 Overall 4	Audit 12M	
PROCESSID **7749**	576		Freq 2	Task 1D	
Check the quotes that we send out for the repairs we have received in. _in term_ x	Goods Out 301232		Risk 2 Overall 4		
PROCESSID **7906**	884		Freq 1	Task 1W	
Obtain Returns paperwork / authorisation from supplier to return Items.	Goods Out 301055 x	In terms	Risk 1 Overall 1		

Repair Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **8022**	92	91	Freq 1	Task 1M	
Reviewing Vandagraph Repair in Intrastats	EX Sales Controller	Managing Director	Risk 2 Overall 2	Task 1M	

300361   299 475