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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 8.5.1	Control of production and service provision The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	
Viamed Ltd ISO13485:201 6 7.5.1	Control of production and service provision Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities.	

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	The organization shall establish and maintain a record (see 4.2.5)	
	for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.	
Viamed Ltd	Installation activities	
ISO13485:201	The organization shall document requirements for medical	
6 7.5.3	device installation and acceptance criteria for verification of	
	installation, as appropriate.	
	If the agreed customer requirements allow installation of the	
	medical device to be performed by an external party other than the organization or its supplier, the organization shall provide	
	documented requirements for medical device installation and	
	verification of installation.	
	Records of medical device installation and verification of	
	installation performed by the organization or	
77:1141	its supplier shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:201	Servicing activities If servicing of the medical device is a specified requirement, the	
6 7.5.4	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	
77 1 T . 1	its supplier shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:201	Validation of processes for production and service provision The organization shall validate any processes for production and	
6 7.5.6	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;	

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- 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 ISO13485:201 6 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.

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	NOTE Further information can be found in ISO 19011.	
Viamed Ltd	Analysis of data	
ISO13485:201	The organization shall document procedures to determine, collect	
6 8.4	and analyse appropriate data to demonstrate the suitability,	
	adequacy and effectiveness of the quality management system.	
	The procedures shall include determination of appropriate	
	methods, including statistical techniques and the extent of their	
	use.	
	The analysis of data shall include data generated as a result of	
	monitoring and measurement and from other relevant sources	
	and include, at a minimum, input from:	
	a) feedback;	
	b) conformity to product requirements;	
	c) characteristics and trends of processes and product including	
	opportunities for improvement;	
	d) suppliers;	
	e) audits;	
	f) service reports, as appropriate.	
	If the analysis of data shows that the quality management system	
	is not suitable, adequate or effective, the organization shall use	
	this analysis as input for improvement as required in 8.5.	
	Records of the results of analyses shall be maintained (see 4.2.5).	

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Answer questions 1-4, Any non conformance generate an Issue.

1. Review Last years Audit. Update processes if required.

Are all follow on Issue resolved satisfactory.

INTRASTATS STOCK MENU – SERVICE VISITS – *Service Visits*. All Active and Single visit services should be shown.

2. Are Any service Visits Over Due

Note Tracking ID 34 in the Example,



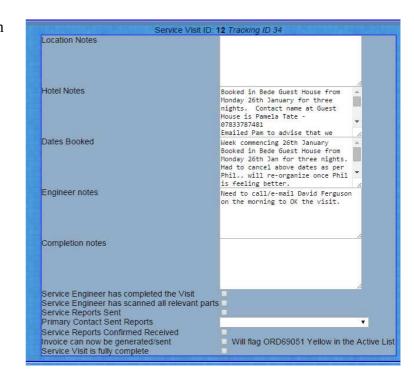
Has the Over due Visit got any Action notes:

Click:



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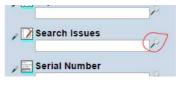
3. Have any over due Visit NOT got any action **notes?**



Drop out of the Service Visit Section, Search Intrastats

In the Subject Contains Words box type: *Check The Service Visit Logs*

You should see a list of system generated tasks to 2 Different employees, Scroll down the list,





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4. Are more than 1 Issue outstanding per user.

5. Any problems found in the Issues system not being addressed.

Sub Processes Linked to Audit

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

List Processes Per Title

Audits					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7889		288	Freq 1	Audit	
To carry out Audit 24		Company		12M	
Servicing Viamed		Secretary	Overall 2		
Office Processes					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5857	233	234	Freq 4	Task 1W	
Ensuring customer onsite	Office Processes	UK Sales	Risk 1	Audit	
service visits are		Controller	Overall	1M	
completed			4		
PROCESSID 7760	607	898	Freq 1	Task 1W	
Send letters to existing	Marketing	Company	Risk 1	Audit	
customers to remind them	Processes	Secretary	Overall	4W	
that a service is due on			1		
their equipment					