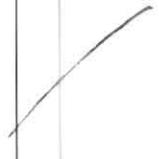
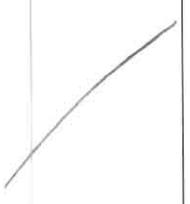


Visited

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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.1.2	<p>Customer focus</p> <p>5.1.2 Customer focus</p> <p>Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:</p> <ul style="list-style-type: none"> a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained. 	
VST Ltd ISO9001:2015 8.5.1	<p>Control of production and service provision</p> <p>The organization shall implement production and service provision under controlled conditions.</p> <p>Controlled conditions shall include, as applicable:</p> <ul style="list-style-type: none"> 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; 	

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	h) the implementation of release, delivery and post-delivery activities	
Viamed Ltd ISO13485:2016 6.4.2	<p>Contamination control As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.</p>	Doc index Roles + titles procedures
Viamed Ltd ISO13485:2016 7.2.1	<p>Determination of requirements related to product The organization shall determine:</p> <ul style="list-style-type: none"> a) requirements specified by the customer, including the requirements for delivery and post delivery activities; b) requirements not stated by the customer but necessary for specified or intended use, as known; c) applicable regulatory requirements related to the product; d) any user training needed to ensure specified performance and safe use of the medical device; e) any additional requirements determined by the organization 	Procedures Doc index Roles + titles Route maps management review
Viamed Ltd ISO13485:2016 7.2.3	<p>Communication The organization shall plan and document arrangements for communicating with customers in relation to:</p> <ul style="list-style-type: none"> a) product information; b) enquiries, contracts or order handling, including amendments; c) customer feedback, including complaints; d) advisory notices. <p>The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.</p>	Doc index Procedures Roles + titles Route map
Viamed Ltd ISO13485:2016 7.5.1	<p>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:</p> <ul style="list-style-type: none"> 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; 	Doc index Procedures Roles + titles purchasing system

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	<p>d) availability and use of monitoring and measuring equipment;</p> <p>e) implementation of defined operations for labelling and packaging;</p> <p>f) implementation of product release, delivery and post-delivery activities.</p> <p>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.</p>	
Viamed Ltd ISO13485:2016 7.5.11	<p>Preservation of product</p> <p>The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:</p> <p>a) designing and constructing suitable packaging and shipping containers;</p> <p>b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.</p> <p>If special conditions are required, they shall be controlled and recorded (see 4.2.5).</p>	<p>Doc index Procedures Barcode System Management Review</p>
Viamed Ltd ISO13485:2016 8.2.4	<p>Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p> <p>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.</p> <p>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</p>	<p>Doc index Audit Calendar Route map Management Review Roles + titles</p>

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	<p>audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p> <p>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).</p> <p>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.</p> <p>NOTE Further information can be found in ISO 19011.</p>	
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	Question								
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.								
2	Does every Order have official customer paperwork. Check 6 orders at random from the Outstanding Customer Orders list.								
	Order No.	CID No.	Customer order number	Check attached documents for customer paperwork and associated docs	Does the customer paperwork match the Invoice	Have these the correct goods scanned to them at shipping	Does the account have an email address or other method for invoice delivery	Initials of the person who entered the order	Initials of the person who checked the order
1	RVM 147449	2905	U024990	✓	✓	✓	✓	KG	SL
2	RVM 147450	3297	CW202316	✓	✓	✓	✓	EM	KG
3	147456	826	12CFD400 043238	✓	✓	✓	✓	KG	CG
4	147451	4224	05-1099 -51746	✓	✓	✓	✓	KG	CG
5	147458	3012	13547221 27	✓	✓	✓	✓	KG	CG
6	147213	4013	200027 685	✓	✓	✓	✓	KG	SG

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3	Have all Queries been dealt with satisfactorily. Check number of Credit Notes last 6 months and if internal error or customer.	4	Normal credits
		5	error credits
		Renewed ok.	
4	Are orders awaiting despatch appropriately packaged and identified.		Y
5	Is appropriate transport arranged, check goods out.		Y
6	Check Ex-works parcels shipping is arranged.		Y
7	Check that the appropriate shipping documents are available for the goods in goods out.		Y
8	Check that the delivery note is attached to the goods.		Y

List Processes Per Title

IT Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 8027 To make sure the pricing on the Shopify web shop is updated when the prices are updated in the companies. Regular checks to ensure all prices are correct.	1204 Marketing Processes 37084 ✓	1215 Company Secretary 302887 ✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 6M	
Warehouse Team Leader					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document

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PROCESSID 7796 To collate all the franking slips that have errors on them and so where not useable. These are returned to Royal mail for a refund of the carriage.	645 Goods Out 311846 ✓	646 Company Secretary 312439 ✓	Freq 2 Risk 1 Overall 2	Task 3M Audit 3M	
PROCESSID 7797 Check order are being picked in order of priority and date.	647 Goods In 316367 ✓	648 Managing Director 312215 ✓	Freq 2 Risk 1 Overall 2	Task 8W Task 2D Audit 3M	
PROCESSID 7798 Review the orders and items shipped per month	649 Managing Director 314747 ✓	650 Company Secretary 312217 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7714 To carry out Audit 01 Picking Packing Viamed	Viamed Audit	24 316310 Company Secretary ✗	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7762 To carry out Audit 01 Picking Packing VST	VST Audit	194 316318 Company Secretary ✗	Freq 1 Risk 2 Overall 2	Audit 12M	

Goods Out

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 5859 audit and snap shot - this is an audit of a part of goods out, listing of the parcels that are sat waiting on a customer response	105 Goods Out 316418 ✓	364 Company Secretary 316723 ✗ in terms	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M	
PROCESSID 7691	491		Freq 2	Task 1D	

317038
* in terms

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Review the sale or return shelf and ship those items.	Goods Out		Risk 1 Overall 2		
PROCESSID 7860 To pick in order orders from the picking screen package the goods ready for dispatch Invoice out the delivery		24 Company Secretary <i>316310</i>	Freq 1 Risk 2 Overall 2	Audit 12M	