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SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.1.2	Customer focus 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: 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 8.2.1	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.	
VST Ltd ISO9001:2015 8.2.2	Determining the requirements for products and services When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers.	
VST Ltd ISO9001:2015 8.2.3.1	The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: a) requirements specified by the customer, including the requirements for delivery and postdelivery activities; b) requirements not stated by the customer, but necessary for the specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed. The organization shall ensure that contract or order requirements differing from those previously	

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	defined are resolved. The customers requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements. NOTE In some situations, such as internet sales, a formal	
	review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.	
VST Ltd ISO9001:2015 8.2.3.2	The organization shall retain documented information, as applicable: a) on the results of the review; b) on any new requirements for the products and services.	
VST Ltd ISO9001:2015 8.2.4	Changes to requirements for products and services The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	
Viamed Ltd ISO13485:2016 5.2	Customer focus Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.	
Viamed Ltd ISO13485:2016 7.2.1	Determination of requirements related to product The organization shall determine: a) requirements specified by the customer, including the requirements for delivery and postdelivery 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	
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).	

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	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.	
V. 11.110012405 2016		
Viamed Ltd ISO13485:2016		
7.2.3	The organization shall plan and document arrangements for	
	communicating with customers in relation to:	
	a) product information;	
	b) enquiries, contracts or order handling, including	
	amendments;	
	c) customer feedback, including complaints;	
	d) advisory notices.	
	The organization shall communicate with regulatory	
	authorities in accordance with applicable	
	regulatory requirements.	
Viamed Ltd ISO13485:2016	Internal audit	
8.2.4		
0.2.4	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.	

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QUESTION:	Y/N
Review Last years Audit Are all follow on Issue resolved satisfactory?	
Are Telephone orders being logged in the call log correctly.	
Are Contact Details being updated in the system correctly and fully. Check 5 of this weeks Invoices: Check the Invoice, ORD customer paperwork and CRM are correct. Stamped, initialled and dated correctly 1. 2. 3. 4. 5.	
Check contacts match to Accounts package. Review 5 contacts.	
Check 6 invoices match between Intrastats and Accounts package. Address, stock, totals, VAT. 1. 2. 3. 4. 5. 6.	
Check sales office filing is done correctly and as per GDPR. Archiving processed correctly.	
Quotes and proformas file used correctly check 4 of each, Box size where relevant, checked as per order, stamped emailed and dated check any over the limit set in VM3COP03 have been signed by a director. Quotes 1. 2. 3. 4. Proformas 1. 2. 3. 4.	

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Sub Processes Linked to Audit 02

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

List Processes Per Title

Product Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5905	418	71	Freq 3	Task 1M	
Check we have consistent pricing across	Director 3 (Steve)	Managing Director	Risk 1	Audit 3M	
the different databases.	ì		Overall 3		
PROCESSID 7697	501	502	Freq 1	Task 12M	
To review the current pricing and impact of increases	Director 3 (Steve)	Managing Director	Risk 2 Overall 2	Audit 12M	
PROCESSID 7893	822		Freq 1	Task 3M	
To confirm the Document index Price Lists	Director 3 (Steve)		Risk 1 Overall 1		
ISO Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7941	1005		Freq 2	Task 12M	
Check Leaflets, Letterhead and other	Managing		Risk 3		
paperwork to see if the correct BSI logo is	Director		Overall 6		
in use. Remove and dispose of all old items if found.					
Ask Catrin to review the website for old					
leaflets.					
Humanmed Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7670	611		Freq 3	Task 1M	
Review of Humanmed sales and orders and	Office Processes		Risk 1		
clear any duplicates or problems.			Overall 3		
PROCESSID 7782	770		Freq 2	Task 3M	
Remove Started But Not Used Order	Managing		Risk 1		
Numbers from intrastats.	Director		Overall 2		
Office Team Leader					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 6956			Freq		
			Risk		
			Overall		

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Sales Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 6921 Usual standard price from price list - but may offer quantity discount for less ordered. This is logged in a memo on opera, dated and initial and review date added where needed.			Freq 1 Risk 1 Overall 1		
PROCESSID 6959 All orders appear on the active list and reviewed daily. Forward orders are those the customer has asked a forward date be put on. Those that become due change from gray to yellow and can be picked.			Freq 1 Risk 1 Overall 1		
PROCESSID 7801 To review the current pricing and impact of increases	653 Office Processes	654 Director 3 (Steve)	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M	
EX Sales Force					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5872 Review the Sale or Return list in intrastats. Ensure it is up to date.	291 EX Sales Controller	293 Managing Director	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
OEM Sales Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7808 To find and Tag any sales that are removed from commissions, as they are break even products for relationships purposes	670 Managing Director	704 Director 3 (Steve)	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
PROCESSID 7894 To check the Current Customer Agreements are still Valid	823 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
UK Sales Force					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5871 Review the Sale or Return list in intrastats. Ensure it is up to date.	292 UK Sales Controller	293 Managing Director	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
PROCESSID 5876 To Collect E.Commerce Cardea And Multiquote Orders	361		Freq 5 Risk 1 Overall 5		

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Accounts Processes					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7872	794		Freq 2	Task 6M	
To review with the banks any embargo	Company		Risk 3		
countries	Secretary		Overall 6		
Audits					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7715		36	Freq 1	Audit 12M	
To carry out Audit 02 Contract Review		Company Secretary	Risk 2		
Viamed			Overall 2		
PROCESSID 7763		187	Freq 1	Audit 12M	
To carry out Audit 02 Contract Review		Company Secretary	Risk 2		
VST			Overall 2		
Vandagraph					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7791	636		Freq 3	Task 1M	
Changing of the prices lists without	EX Sales		Risk 2		
informing the sales team.	Controller		Overall 6		
Issue to check these are current					
*Vandagraph is not an ISO company					
· vandagraph is not an 15O company					
Goods Out					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 6954	905	906	Freq 1	Task 1W	
To check the back orders in the tray in	Goods Out	Company Secretary	Risk 1	Audit 1M	
goods out and check the active list back			Overall 1		
orders has been reviewed					
Office Processes					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 2		668	Freq 2	Audit 3M	
Office Answering taking calls and either			Risk 1		
dealing with the enquiry or passing the call			Overall 2		
onto someone who can,					
or making a call log for someone to return					
a call					
PROCESSID 3			Freq		
What to do when we have guests			Risk		
			Overall		
PROCESSID 4			Freq		

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	I		1	1	
Offering guests a drink and/or snacks/lunch if appropriate.			Risk Overall		
PROCESSID 5 Enter Customer orders into the system, Checking Orders entered into the system so the order drops into the Active / Order picking list			Freq 1 Risk 1 Overall 1		
PROCESSID 7 Process to check customer orders and enable picking		901 Office Processes	Freq 1 Risk 1 Overall 1	Audit 1W	
PROCESSID 8 To contact customers who require order confirmations and let them know their orders have been received.			Freq 1 Risk 1 Overall 1		
PROCESSID 14 Ensuring that fax reports have been generated for both sent and received faxes and ensuring there is paper in the fax machine	367	411	Freq 4 Risk 1 Overall 4		
PROCESSID 36 Invoices are emailed to customers	430 Office Processes	362 Company Secretary	Freq 4 Risk 1 Overall 4	Task 1D Audit 1W	
PROCESSID 37 Viamed has a consignment stock with West Yorkshire Ambulance,	348	349	Freq 4 Risk 1 Overall 4		
We scan stock to a shelf, then send them the consignment stock As and when they use stock each week we do a rational and invoice them for the used stock and replenish the consignment stock. WYA Stock check via the website.					
We can now check their stock agrees with ours.					
PROCESSID 5875 Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox	239 Office Processes	401	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID 5882 Humanedmed post is received, it needs to be forwarded to Humanmed UK Sales Manager	382 Office Processes	383 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 4W	
PROCESSID 5891 To process the Repair Quotes And Orders as they come in.		536	Freq 3 Risk 1 Overall 3		
PROCESSID 5892 Checking the eBay and Amazon accounts	397 Office Processes	398 Office Processes	Freq 5 Risk 1	Task 1D Audit 1W	

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for orders that have not been emailed to the main inbox and checking to see if there are			Overall 5	
messages or questions.				
PROCESSID 5893 Answering any questions that are asked via the website from within Intrastats	643 Office Processes	396 Company Secretary	Freq 5 Risk 1 Overall 5	Task 1D Audit 1M
PROCESSID 5894 Check the Active Back orders ensure no orders get missed	896 Office Processes	897 Managing Director	Freq 1 Risk 1 Overall 1	Task 1D Audit 6M
PROCESSID 5895 Ensuring that the allocated tasks are being completed	776 Office Processes	777	Freq 3 Risk 1 Overall 3	Task 1W Audit 1M
PROCESSID 5896			Freq Risk Overall	
PROCESSID 5897 Task to Frank outgoing Mail	564 Goods Out	568	Freq 5 Risk 1 Overall 5	Task 1D Audit 6M
PROCESSID 5899 Chase outstanding Quotes and Proformas	409 Office Processes	410	Freq 5 Risk 1 Overall 5	Task 1W Audit 1M
PROCESSID 5913 Checking the logistics mailbox from within and the main inbox for outstanding Humanmed orders.	465 Office Processes	466 Office Processes	Freq 4 Risk 1 Overall 4	Task 1D Audit 1M
PROCESSID 5943 Checking the Cardea and Multiquote websites for outstanding orders or requests	530 Office Processes	279 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M
PROCESSID 5944 As part of the office jobs list - chase customers that have not ordered from us in a set timescale Specific lost customer are added to the list to be chase when the office have time			Freq 1 Risk 1 Overall 1	
PROCESSID 5945			Freq Risk Overall	
PROCESSID 5946			Freq Risk Overall	
PROCESSID 5947			Freq Risk Overall	
PROCESSID 5948 Adding customer accounts to account management software		669 Company Secretary	Freq 3 Risk 1 Overall 3	Audit 12M
PROCESSID 5949 Inputting the accurate data on to our pre-	903 Goods Out	904 Company Secretary	Freq 1 Risk 3	Task 1W Audit 1M

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printed credit card slips for processing on dispatch of good. Secure storing and processing			Overall 3	
PROCESSID 6958			Freq Risk Overall	
PROCESSID 7675			Freq Risk Overall	
PROCESSID 7676 Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers	504 Office Processes	505 Office Processes	Freq 2 Risk 1 Overall 2	Task 1D Audit 1W
PROCESSID 7678 Checking the Catalog 360 Circle website for outstanding orders or requests	478 Office Processes	531 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M
PROCESSID 7686 Check that outstanding orders with unresolved issues are being followed up and addressed	487 Office Processes	569 Company Secretary	Freq 5 Risk 1 Overall 5	Task 1D Audit 1M
PROCESSID 7696 Emailing Notifications of shipments	496 Office Processes	537 Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W
PROCESSID 7709 Ensure invoices are generated for shipped orders	523 Office Processes	524	Freq 5 Risk 1 Overall 5	Task 1D Audit 1M
PROCESSID 7710			Freq Risk Overall	
PROCESSID 7712 Review the payments received to ensure proformas can be shipped	528 Office Processes	529 Office Processes	Freq 3 Risk 1 Overall 3	Task 1D Audit 1W
PROCESSID 7734 To make sure Humanmed orders are processed in a timely manner			Freq 1 Risk 1 Overall 1	
PROCESSID 7735 Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and the item(s) is returned as appropriate	549 Office Processes	550 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M
PROCESSID 7758 Check the emails for orders from GHX	603 Office Processes	604 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M
PROCESSID 7761 Emailing Notifications of shipments	620 Office Processes	621 Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W
PROCESSID 7783 Process of PDF ing Invoices into the system for easy of use in the future and the	612 Office Processes	613 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M

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Emailing of Invoices to customers				
PROCESSID 7795 Answering any questions that are asked via the website from within Intrastats	643 Office Processes		Freq 5 Risk 1 Overall 5	Task 1D
PROCESSID 7822 To check we have the stock available to supply our customer Oxylink. NOTE THIS PROCESS HAS BEEN STOPPED.	708	709	Freq 3 Risk 1 Overall 3	
Part number has been superseded				
PROCESSID 7936 Checking external system for orders	990 Office Processes	991 Marketing Processes	Freq 2 Risk 2 Overall 4	Task 1W Audit 1M