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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 post delivery 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 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	

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	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	The organization shall retain documented information, as applicable: a)	
ISO9001:2015 8.2.3.2	on the results of the review;	
	b) on any new requirements for the products and services.	
VST Ltd	Changes to requirements for products and services	
ISO9001:2015 8.2.4	The organization shall ensure that relevant documented information is	
1507001.2013 6.2.4	amended, and that relevant persons are made aware of the changed	
	requirements, when the requirements for products and services are changed.	
17. 1T.41		
Viamed Ltd	Customer focus	
ISO13485:2016 5.2	Top management shall ensure that customer requirements and applicable	
	regulatory requirements are determined and met.	
Viamed Ltd	Determination of requirements related to product	
ISO13485:2016 7.2.1	The organization shall determine:	
	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	
Viamed Ltd	Review of requirements related to product	
ISO13485:2016 7.2.2	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	Communication	
ISO13485:2016 7.2.3	The organization shall plan and document arrangements for	
15015705.2010 /.2.5	communicating with customers in relation to:	
ĺ	communicating with customers in relation to.	

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	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	Internal audit	
ISO13485:2016 8.2.4	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.	

QUESTION:	Y/N
Review Last years Audit Are all follow on Issue resolved satisfactory?	
Are Telephone orders being logged in the call log correctly.	

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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.  1. 2. 3. 4. 5.	
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 <b>5905</b> Check we have consistent pricing across the different databases.	418 Director 3 (Steve)	71 Managing Director	Freq 3	Task 1M Audit 3M	T (OCC) / ISSUES
PROCESSID <b>7697</b> To review the current pricing and impact of increases	501 Director 3 (Steve)	502 Managing Director	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M	
PROCESSID <b>7893</b> To confirm the Document index Price Lists	822 Director 3 (Steve)		Freq 1 Risk 1 Overall 1	Task 3M	
ISO Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID <b>7941</b> Check Leaflets, Letterhead and other paperwork to see if the correct BSI logo is in use. Remove and dispose of all old items if found. Ask Catrin to review the website for old leaflets.	1005 Managing Director		Freq 2 Risk 3 Overall 6	Task 12M	
Humanmed Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID <b>7670</b> Review of Humanmed sales and orders and clear any duplicates or problems.	611 Office Processes		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID <b>7782</b> Remove Started But Not Used Order Numbers from Intrastats.	770 Managing Director		Freq 2 Risk 1 Overall 2	Task 3M	
Sales Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID <b>7801</b> 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	

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EX Sales Force					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5872	291	293	Freq 3	Task 1M	
Review the Sale or Return list in intrastats. Ensure it is up to date.	EX Sales Controller	Managing Director	Risk 2 Overall 6	Audit 3M	
OEM Sales Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7808	670	704	Freq 3	Task 1M	
To find and Tag any sales that are removed from commissions, as they are break even products for relationships purposes	Managing Director	Director 3 (Steve)	Risk 1 Overall 3	Audit 3M	
PROCESSID 7894	823	1067	Freq 1	Task 6M	
To check the Current Customer Agreements are still Valid	Director 3 (Steve)	Managing Director	Risk 1 Overall 1	Audit 12M	
UK Sales Force					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5871	292	293	Freq 3	Task 1M	
Review the Sale or Return list in intrastats. Ensure it is up to date.	UK Sales Controller	Managing Director	Risk 2 Overall 6	Audit 3M	
PROCESSID 5876	361		Freq 5		
To Collect E.Commerce Cardea And Multiquote Orders			Risk 1 Overall 5		
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 countries	Company Secretary		Risk 3 Overall 6		
Audits					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7715		36	Freq 1	Audit	
To carry out Audit 02 Contract Review Viamed		Company Secretary	Risk 2 Overall 2	12M	
PROCESSID 7763		187	Freq 1	Audit	
To carry out Audit 02 Contract Review VST		Company Secretary	Risk 2 Overall 2	12M	

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Vandagraph					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7791 Changing of the prices lists without informing the sales team. Issue to check these are current	636 EX Sales Controller		Freq 3 Risk 2 Overall 6	Task 1M	
*Vandagraph is not an ISO company					
Goods Out					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID <b>6954</b> To check the back orders in the tray in goods out and check the active list back orders has been reviewed	905 Goods Out	906 Company Secretary	Freq 1 Risk 1 Overall 1	Task 1W Audit 1M	
Office Processes					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 2 Office Answering taking calls and either dealing with the enquiry or passing the call onto someone who can, or making a call log for someone to return a call		668 Office Processes	Freq 2 Risk 1 Overall 2	Audit 3M	
PROCESSID 7 Process to check customer orders and enable picking		901 Office Processes	Freq 1 Risk 1 Overall 1	Audit 1W	
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 <b>36</b> Invoices are emailed to customers	430 Office Processes	362 Company Secretary	Freq 4 Risk 1 Overall 4	Task 1D Audit 1W	
PROCESSID <b>37</b> 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.					

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WYA Stock check via the website.				
We can now check their stock agrees with ours.				
PROCESSID <b>5875</b> Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox	239 Office Processes	401 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M
PROCESSID <b>5882</b> 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 <b>5891</b> To process the Repair Quotes And Orders as they come in.		536	Freq 3 Risk 1 Overall 3	
PROCESSID <b>5892</b> Checking the eBay and Amazon accounts for orders that have not been emailed to the main inbox and checking to see if there are messages or questions.	397 Office Processes	398 Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W
PROCESSID <b>5893</b> 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 <b>5894</b> 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 <b>5895</b> Ensuring that the allocated tasks are being completed	776 Managing Director	777 Office Processes	Freq 3 Risk 1 Overall 3	Task 1W Audit 1M
PROCESSID <b>5897</b> Task to Frank outgoing Mail	564 Goods Out	568 Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 6M
PROCESSID <b>5899</b> Chase outstanding Quotes and Proformas	409 Office Processes	410 Office Processes	Freq 3 Risk 1 Overall 3	Task 1W Audit 1M
PROCESSID <b>5913</b> 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 <b>5943</b> 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 <b>5948</b> Adding customer accounts to account management software		669 Company Secretary	Freq 3 Risk 1 Overall 3	Audit 12M
PROCESSID <b>5949</b> 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 <b>7676</b> Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers  NO LONGER REQUIRED AS DONE BY	504	505	Freq 2 Risk 1 Overall 2		
THE SYSTEM AUTOMATICALLY					
PROCESSID <b>7678</b> 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 <b>7686</b> 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 <b>7696</b> Emailing Notifications of shipments	496 Office Processes	537 Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W	
PROCESSID <b>7709</b> Ensure invoices are generated for shipped orders	523 Office Processes	524 Office Processes	Freq 5 Risk 1 Overall 5	Task 1D Audit 1M	
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 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 Emailing of Invoices to customers	612	613	Freq 4 Risk 1 Overall 4		
NOW DONE AUTOMATICALLY					
PROCESSID <b>7795</b> Answering any questions that are asked via the website from within Intrastats	643 Office Processes		Freq 5 Risk 1 Overall 5	Task 1D	
PROCESSID <b>7822</b> To check we have the stock available to	708	709	Freq 3 Risk 1		

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supply our customer Oxylink.			Overall 3		
NOTE THIS PROCESS HAS BEEN STOPPED.					
Part number has been superseded					
PROCESSID <b>7936</b> Checking external system for orders	990 Office Processes	991 Marketing Processes	Freq 2 Risk 2 Overall 4	Task 1W Audit 1M	
PROCESSID <b>7953</b> To Send Vandagraph Delivery notifications	1043 Office Processes		Freq 1 Risk 1 Overall 1	Task 1D	
PROCESSID <b>7955</b> Vandagraph Shipper SignOff Collection List	1044 Office Processes		Freq 1 Risk 1 Overall 1	Task 1D	