Internal Audit Check list			
Viamed Ltd Contract Review and Sales Order Processing			
Created:	17/May 1995	**Audit No 02**	VOP12
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Audit Date		Auditor	

SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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 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 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 7.2.3	**Communication** 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 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.	

	QUESTION:		**Y/N**
1	Review Last years Audit Are all follow on Issue resolved satisfactory?		
2	Are Telephone orders being logged in the call log correctly.		
3	Are Contact Details being updated in the system correctly and fully. Check 6 of this weeks Invoices, different companies. Check the Invoice, customer paperwork and CRM are correct. 1. 2. 3. 4. 5. 6.		

4	Check contacts match to Accounts package. Review the same as question 3. 1. 2. 3. 4. 5. 6.		
5	Check 6 invoices match between Intrastats and Accounts package. Use the same as Question 3. Address, stock, totals, VAT. 1. 2. 3. 4. 5. 6.		
6	Paperwork – All is now digital but double check in the sales office and around both buildings for paperwork that should be disposed of securely. Ensure it is processed as per GDPR, not left lying around and when finished with shredded or archived correctly. Review Tasks ID1087, ID1086, ID508, ID509		
7	Quotes and proformas – check 4 of each, check the addresses, stock, and quantities to the customer paperwork. Check any over the limit set in VM3COP03 have been approved by a director. Quotes 1. 2. 3. 4. Proformas 1. 2. 3. 4.		

8	Quotes and proformas – check these are being reviewed regularly. Note any that have not been reviewed within the last 2 months. Note these below and issue the person responsible.		

Sub Processes Linked to Audit 02

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