Internal Audit Check list			
VIAMED LTD DOCUMENT CONTROL			
Created:	17/May 1995	**Audit No 10**	
Revised:	12 June 2024	Michael Lamb	Page 1 of 12
Audit Date	27/6/24	Auditor Helen Lamb	

Documentation control is being moved from a paper system to Intrastats
Many of the questions asked are now superfluous as the checks are carried out automatically, and recorded automatically. The hard copies are being replaced and Archived.

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 4.1.1	**Quality management system** The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.	Doc index Roles + titles Scope
Viamed Ltd ISO13485:2016 4.1.6	**Quality management system** For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. 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. Records of such activities shall be maintained (see 4.2.5).	Doc index procedures Roles + titles
Viamed Ltd ISO13485:2016 4.2	**Documentation requirements**	
Viamed Ltd ISO13485:2016 4.2.1 General	**Documentation requirements** The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	Doc index Route map
Viamed Ltd ISO13485:2016	**Documentation requirements** The organization shall document a quality manual that includes:	

4.2.2 Quality manual	a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	Doc index Roles + titles procedures
Viamed Ltd ISO13485:2016 4.2.4 Control of documents	**Documentation requirements** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5. A documented procedure shall define the controls needed to: a) review and approve documents for adequacy prior to issue; b) review, update as necessary and re-approve documents; c) ensure that the current revision status of and changes to documents are identified; d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled; g) prevent deterioration or loss of documents; h) prevent the unintended use of obsolete documents and apply suitable identification to them. The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable	Doc index Procedures Roles + titles tech files
Viamed Ltd ISO13485:2016 4.2.5 Control of records	**Documentation requirements** Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable. The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from	Doc index procedures Roles + titles

	the medical device release by the organization.	
Viamed Ltd ISO13485:2016 5.6.1	**General** The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained	
Viamed Ltd ISO13485:2016 7.1	**Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971.	Doc index Tech files management Review Route map QA system Barcode tracking
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	management Review Doc index procedures Route map Training Records

	that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	
Viamed Ltd ISO13485:2016 7.5.6	**Validation of processes for production and service provision** The organization shall validate any processes for production and 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; 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).	Doc index Barcode system Procedures Management Review.
Viamed Ltd ISO13485:2016 7.5.9.1	**General** The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5).	Doc index Procedures
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	Doc index Audit calendar Route map Roles + titles

	(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.	
Viamed Ltd ISO13485:2016 8.2.5	**Monitoring and measurement of processes** The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.	Doc index management Renew Route map Roles + titles.
Viamed Ltd ISO13485:2016 8.5.2	**Corrective action** The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; f) reviewing the effectiveness of corrective action taken. Records of the results of any investigation and action taken shall be maintained (see 4.2.5).	Management Renew issues Renew meetings Doc index Intrastats.

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	QUESTION:	**RESPONSE:**	
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
2	Is there sole responsibility for company procedures and other documentation.	IT director has sole access to Intrastats system	Y
3	Verify that documentation is checked prior to formal approval and issue and authorisation is unique.	Intrastats	Y
4	Verify that all personnel have access to their relevant areas of the documentation.	Intrastats	Y
5	Verify that amendments can be requested and are controlled by Date issue. are updated Electronically and old copies Archived.	Intrastats	Y

6	Check that the C.E. files are maintained by sole responsibility.		Y
7	Check that obsolete data in the files is Archived	Intrastats also Archives store	Y
8	Are manufacturers data sheets supplied the latest issue. Supplier Review.	Intrastats	Y
9	Verify that checks are made to ascertain the latest issue data sheets are supplied after design change / modification (from suppliers).	Intrastats	Y
10	Are Intrastat documents regularly backed-up and secure offsite Task ID (452) #331372 ✓	Intrastats – Roles and Responsibilities: Task ID (452)	Y
11	Check that the document register is complete and adequate.	Intrastats	Y
12	Verify that records are easily retrievable for information and analysis.	Intrastats on workstation	Y
13	Are printed copies of production procedures the latest issue status.	No printed copies Not printed	Y
14	Is the procedure for ensuring only the latest issue of drawings and documentation available working correctly Check 6 items in the Index. Task ID (371)	Intrastats. Task ID (371) 330629 ✓ in terms	Y
15	Are quality records properly filed and easily retrievable.	Intrastats	Y
16	Is the Company procedures Manual the latest version. Automark	Intrastats	Y
17	Has the organisation chart changed.		N
18	Has the responsibility descriptions changed.	Intrastats – Roles and Responsibilities	N
19	Stock linked document – have documents been linked to stock correctly. ISO – Document Index Admin – Complete Amendment Log – look down the list for stock related documents, then see if the stock link is present. The list shows the last 3 months.	went to Page 6 mid June Yes	Y
20	Duplicate Documents – Task ID (370) – ISO – Documentation Index Admin – find duplicate files. This should be empty. Make a note of the number and dates. #332690 ✓ in terms		Y

Sub Processes Linked to Audit 10
Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Managing Director				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **5877** To review the numbers of various departments. Showing increasing / reducing staff	Task: 114 Managing Director 334353 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	

requirements Check Audit Roles Titles and Processes in Employee Roles and Titles. Check the Page for Red Crosses and potentially missing objectives	Audit :561 Company Secretary 309316			
ISO Controller				
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **5890** Ensure the online available copies of our ISO standards are upto date	Task: 463 Marketing Processes 331875 Audit :464 Managing Director 333835	Freq 3 Risk 1 Overall 3	Task 1M Audit 6M	
IT Controller				
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **44** Encrypt data sent back and forth to Intrastats so it can be used off site	Task: 412 Managing Director 305591 Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **52** Keeps a month or so backup emails	Task: 368 Audit :417	Freq 2 Risk 1 Overall 2		
PROCESSID **53** Maintain the Online Email boxes currently Google and Goldmine	Task: Audit :902 336277 Marketing Processes	Freq 1 Risk 1 Overall 1	Audit 1W	
PROCESSID **7126** Fix general errors in intrastats such as Spelling errors or columns not lining up	Task: 458 Managing Director 334369 Audit :	Freq 2 Risk 1 Overall 2	Task 1M	
PROCESSID **7129** Update the online Cross reference guides with latest intrastats data.	Task: 462 Managing Director 331874	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

	Audit :457 Director 3 (Steve) 330254 ✗ in terms			
PROCESSID **7130** To Review the L Drive Library is in sync with Intrastats Documentation TASK DISCONTIUNED, L Drive has been replaced with Intrastats	Task: 791 Audit :	Freq 3 Risk 1 Overall 3		
PROCESSID **7672** To take a copy of the important data off-site thats not being automatically backup by the system, Currently T Drive being the primary files to be backed up. Changed routine to Monthly, as only T drive is now being backed up, all other files automatically being backed up remotely	Task: 452 Office Processes 334255✗ in terms Audit :453 Company Secretary 331202✓	Freq 2 Risk 2 Overall 4	Task 1M Audit 3M	
PROCESSID **7700** Maintain Domains for websites	Task: 510 Office Processes 332931 ✗ in terms Audit :	Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7739** Intrastat Changes updates. Logging system to enable roll back should anything break	Task: 562 Managing Director 334388✓ Audit :	Freq 2 Risk 1 Overall 2	Task 1W	
PROCESSID **7987** To Export Telephone logs from the phone system to intrastats	Task: 1120 Managing Director 334629✓ Audit :1121 Company Secretary 328069✓	Freq 1 Risk 1 Overall 1	Task 1W Audit 6M	
Maintenance Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **8039** Weee Report Due Vandagraph Annual	Task: 77 Managing Director 316313✓ Audit :	Freq 1 Risk 1 Overall 1	Task 12M	

Documentation And Records Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **59** Check the Document Index for any out of date documents,	Task: 371 Managing Director 333328 x in forms Audit :372 Company Secretary 322369 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 6M	
PROCESSID **5851** Removal of Duplicate documents	Task: 370 Office Processes 332690 x in forms. Audit :369 Company Secretary 321453 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 6M	
PROCESSID **5940** Generate the Thumbs nails for the document Index	Task: 155 Managing Director 334357 ✓ Audit :	Freq 2 Risk 1 Overall 2	Task 1M	
PROCESSID **7992** Remind staff to supply any new coshh and or datasheet to technical manager to be added to the system.	Task: 1129 Company Secretary 320444 ✓ Audit :1130 Managing Director 302493 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **8001** Verifiy stock is being linked to documents when required	Task: 1147 Managing Director 323016 ✓ Audit :1148 Company Secretary 332599 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **8032** Review contact related external documents confirm current versions	Task: 1223 Managing Director 333231 x in forms Audit :1224 Office Processes 322213 ✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M	
PROCESSID **8050**	Task: 214	Freq 1	Task 12M	

333819 x in forms

Master Indemnity Register Viameds products and public liability insurance renews every year on 29th June. Send proof of insurance (To Whom It May Concern letter obtained from Thomas Cook and Son) to the following contacts to maintain our registration on the Department of Health Master Indemnity Register and the regional registers: - Department of Health (covers England, Wales and NI) - mia@dhsc.gov.uk cc pat.kavanagh@dhsc.gov.uk - Health Facilities Scotland - central mailbox for all NHS Scotland MIA correspondence nss.miascotland@nhs.scot - NHS Wales Shared Services Partnership - Procurement Services - MIAWales@wales.nhs.uk cc matthew.jurjavcic@wales.nhs.uk	UK Sales Controller Audit :	Risk 1 Overall 1		
PROCESSID **8053** Document in intrastats vm3cop02.1 Whos Who check its current and upto date	Task: 321 Company Secretary 322874 ✓ Audit :	Freq 1 Risk 1 Overall 1	Task 6M	
Product Controller				
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **7863** To confirm the current repairs codes for various products in the system are up to date and available to office members of staff.	Task: 772 Director 3 (Steve) 308564 ✓ Audit :773 Managing Director 308679 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
Sales Controller				
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **8029** Send Inter Company Invoices to Jean. Download from sales page and email.	Task: 1214 Managing Director 333897 ✓ Audit :1217 303912 ✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M	

	Company Secretary			
Audits				
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **7722** To carry out Audit 10 Documentation Control Viamed	Task: Audit :27 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
Accounts Processes				
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **7922** To back up Journals and other docs that have been saved in Emilys users folder. Journal are checked monthly so they need to be in the Journals folder to be able to be checked.	Task: 934 332534 Audit :	Freq 1 Risk 2 Overall 2		
Office Processes				
Process Scope	**Roll Task Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **9** Distribute recieved faxs	Task: 824 Audit :	Freq 1 Risk 1 Overall 1		
PROCESSID **10** Distribute Emails	Task: Audit :366 Managing Director	Freq 3 Risk 1 Overall 3	Audit 1M	
PROCESSID **11** Distibuting incoming post to correct person	Task: 599 Company Secretary 334603 Audit :	Freq 3 Risk 1 Overall 3	Task 1D	
PROCESSID **15** Paperwork to be filed in the correct order	Task: 567 Company 332543	Freq 1 Risk 1	Task 31D Audit 12M	

	Secretary Audit :1242 Managing 334120✓ Director	Overall 1		
PROCESSID **5901** To link new calls to Contacts in the CRM	Task: 404 Office Processes 334570 ✗ Audit :405 Company 333047✓ Secretary	Freq 2 Risk 1 Overall 2 in terms	Task 1W Audit 1M	
PROCESSID **7693** Collect the filing form the warehouse	Task: 506 Goods Out 334379✓ Audit :507 333560✗ Office Processes	Freq 1 Risk 1 Overall 1 in terms	Task 1W Audit 1M	
PROCESSID **7699** Shredding of sensitive information	Task: 508 Office Processes 335663✓ Audit :509 Office Processes	Freq 1 Risk 1 Overall 1 333192✓	Task 2W Audit 1M	
PROCESSID **7705** Checking if a customer has uploaded an order directly to our website	Task: 517 Audit :518	Freq 2 Risk 2 Overall 4		
PROCESSID **7711** Download the most recent bank statement from the bank website	Task: 526 Office Processes 334591 ✗ Audit :527 Company 334383✓ Secretary	Freq 2 Risk 1 Overall 2 in terms	Task 1D Audit 1W	