Internal Audit Check list			
VIAMED LTD GOODS INWARDS AND PRODUCT IDENTITY			
Created:	17/May 1995	**Audit No 09**	VM3/COP05/06 VOP07
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Audit Date	23/3/26	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 6.3	**Infrastructure** The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained	management review Feedback QA system Doc index
Viamed Ltd ISO13485:2016 6.4.2	**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.	Roles + titles Doc index
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:	Doc index Tech files Route map management Review.

	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.	
Viamed Ltd ISO13485:2016 7.4.1	**Purchasing process** The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a) based on the supplier's ability to provide product that meets the organizations' requirements; b) based on the performance of the supplier; c) based on the effect of the purchased product on the quality of the medical device; d) proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).	Doc index Roles + titles Supplier Review
Viamed Ltd ISO13485:2016 7.4.2	**Purchasing information** Purchasing information shall describe or reference the product to be purchased, including as appropriate: a) product specifications; b) requirements for product acceptance, procedures, processes and equipment; c) requirements for qualification of supplier personnel;	Procedures Supplier Review

	d) quality management system requirements. The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).	Doc index Purchasing System Roles + titles
Viamed Ltd ISO13485:2016 7.4.3	**Verification of purchased product** The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.5).	Purchasing System Supplier Renew Roles + titles
Viamed Ltd ISO13485:2016 7.5.1	**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: 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; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides	Roles + titles management Renew Doc index

	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.	
Viamed Ltd ISO13485:2016 7.5.10	**Customer property** The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).	Doc Index Procedure Barcode System
Viamed Ltd ISO13485:2016 7.5.8	**Identification** The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.	Barcode System Calibration System Tech files QA system
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	Doc Index Route Map management review Roles + tasks.

	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.	
Viamed Ltd ISO13485:2016 8.3.1	**General** The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5)	Doc index Issues QA System Bar codes Roles + tasks

	QUESTION:	**RESPONSE:**	**Y/N**
1	Check all issues from the previous audit are completed. NO Non Conformances.	Nothing outstanding	Y
2	Check that stock booked in, is transferred to relevant location with Barcodes. All stock opened should have barcodes or a Hold label with Issue number.		Y
3	Verify that goods are checked against the original Purchase Order and Supplier delivery Note. Then entered into the Deliveries in Intrastats. Check the Supplier delivery Note has been marked to show quantity delivered and ticked off. Then stamped with the dated received stamp and initialled		

	Check 5 separate stock items from the good awaiting QA shelf. Pick am item, put the ID in Serial Number search to get the Purchase Order Number and go to the Delivery Notes file. 1. PVM 5004 2. PVM 4912 3. PVM 4909 4. PVM 4748 5. PVM 4835	all good No problems found.	Y
4	Check that incorrect goods, non-conforming parts and those with queries are segregated, identified as such and put on hold awaiting action. These must all have a HOLD label with Issue Number, date and initials. List any that are unidentified.		Y
5	Are goods identified Hold when awaiting action and in the appropriate area. Those on a none hold shelf should have a HOLD label with Issue Number, date and initials. List any items that are unidentified.		Y
6	Check the Deliveries on Intrastats has been filled in correctly. Look at the last week. Check for purchase order numbers, stock types, quantities, SRS's etc. In Stock – Deliveries		Y
7	Are all incoming consignments logged in the Deliveries on Intrastats. Check 5 random Delivery Notes/Purchase orders for the previous 3 months from different companies. 1. PVM 5004 2. PVM 4909 3. PVM 4748 4. PVM 4835 5. PVM 4912		Y
8	Check that items, once through QA are packaged correctly and labelled appropriately. List 5 checked. 1. PVM 5004 2. PVM 4909		Y

	3. PVM4748 4. PVM 4835 5. PVM4912		Y
9	Check that goods in the Goods Inward area can be identified and have not been left unprocessed for more than two days. List any found. None found		Y
10	Verify that repairs booked in are identified by Service Repair Number (SRN) and Service Repair Sheet (SRS). That the appropriate information is included in the ducket prior to moving to workshop. Check all the duckets on the Repairs shelf in Goods In. List any without the correct paperwork. Nothing unidentified	all have paperwork	Y
11	Check that the relevant information is entered onto Intrastats. Check 5 SRS's. Returns – Returns Completed or Repairs not completed. 1. SRS69409 ✓ 2. SRS 69400 ✓ 3. SRS 69366 ✓ 4. SRS 69363 ebay less info available ✓ 5. SRS 69360 ✓		Y
12	Check the building for unidentified or unmarked goods without a hold label. The label should include an Issue number, date and initials. List any that are found.	None found	Y
13	Are goods identified Hold when awaiting action and in the appropriate area. HOLD label must have Issue Number, date and initials. List any items that are unidentified.	Nothing unidentified	Y
14	Check that Return to Supplier is complete and up to date as per Intrastats. Task ID (66) Search issue to see if up to date.		Y
15	Check that there are no goods over one month left waiting to be returned on the shelf.		

16	Check Meeting in Intrastats is completed quarterly by MD.		
17	Check that completed stock is identified as such by Barcodes and the location is correct. Check 5 stock items at random. stock id loc 1. 4310009 - 2872620 - 838087 ✓ 2. 0014752 - 2761558 - 837845 ✓ 3. 3210070 - 2858480 - 837884 ✓ 4. 0031257 - 529881 → 33186 ✓ 5. 2530049 - 2284144 - 126483 ✓		Y
17	Check that storage areas are adequate for safe handling and easy access to goods. Walk round all stock areas and note any restriction/problems.		Y

Sub Processes Linked to Audit 09

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

List Processes Per Title

Clone from Docid

Managing Director				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	**Notes**
PROCESSID **7830** To review the Quantities of Failed product per Stock reference Passing through the Q.A. system	Task: 727 393436 ✓ Goods In Audit :729 387402 ✓ Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
IT Controller				
Process Scope	**Roll Task**	**Risk**	**Action**	**N**

	Roll Audit			Notes
PROCESSID **6838** To find and correct opera when it reads Negative stock values. NOT REQUIRED ANYMORE Opera	Task: ~~461~~ Audit :	Freq 1 Risk 1 Overall 1		
Product Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **5854** To update and maintain the Stock FAQ list	Task: 231 393268 Director 3 (Steve) Audit :374 394955 Managing Director	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M	
Marketing Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **6894** Maintenance and research of cross reference tables	Task: 673 394992 x Marketing Processes in terms Audit :674 392898 x Director 3 (Steve) in	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
Sales Controller	terms			
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **57** To Review Memos on Stock references	Task: 207 394341 x Director 3 (Steve) in terms	Freq 2 Risk 1	Task 1M Audit 3M	

tagged as Temporary	Audit :206 390417 ✓ Managing Director	Overall 2		
Warehouse Team Leader				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	**Notes**
PROCESSID **7826** To Receive Goods from Suppliers	Task: 915 392906 ✓ Goods Out Audit :734 392761 ✓ Office Processes	Freq 2 Risk 2 Overall 4	Task 1M Audit 3M	
PROCESSID **7903** Empty Warehouse depleted sensor bin into Bin in cage and record weights in intrastats where relevant	Task: 878 392136 ✓ Goods In Audit :879 387484 ✓ Office Processes	Freq 1 Risk 1 Overall 1	Task 1M Task 3W Audit 6M	
PROCESSID **7914** To download or pdf the proof of deliveries This is not needed at present. It was brought in prior to covid.	Task: 917 370064 ✓ Company Secretary Audit :918 340753 ✓ Office Processes	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
PROCESSID **7915** To ensure we have enough items of particular stock for certain customer whom can and do place large orders of regular stock,	Task: 921 395380 ✓ Goods In Audit :	Freq 1 Risk 1 Overall 1	Task 1W	
PROCESSID **7917** Check stock requirements for human med Stock NO Longer required	Task: ~~920~~ Audit :	Freq 1 Risk 1 Overall 1		
PROCESSID **7923** To Review and tidy up any outstanding RMAs that have been resolved by Supplier credit notes	Task: 935 395250 ✗ in terms Goods Out Audit :936 393903 ✓ Goods In	Freq 1 Risk 1 Overall 1	Task 2W Audit 1M	
PROCESSID **7957** Warehouse requests for stock to be reviewed, any shortages to be ordered or produced	Task: 1047 395014 ✗ in terms Director 3 (Steve) Audit :	Freq 1 Risk 1 Overall 1	Task 1M	

with a production Job			
PROCESSID **7967** To count the final year end stock for VST	Task: 1084 392645 ✗ Goods In items Audit :	Freq 2 Risk 2 Overall 4	Task 12M
PROCESSID **8006** Visually check the warehouse for unidentifed stock	Task: 1158 391159 ✓ Company Secretary Audit :1159 365856 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID **8009** Randomly test/list 5 stock Items from finished shelfs. to verify their loction in intrastats, Check for Barcode label. check serial number or batchnumber where applicable to the barcode. confirm packaged suitably.	Task: 1164 389731 ✓ Office Processes Audit :1165 391160 ✓ Production Processes	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M
PROCESSID **8010** Verify Ebay stock is scanned to the correct shelf.	Task: 1166 389732 ✓ Marketing Processes Audit :1167 394398 ✓ Office Processes items	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M
PROCESSID **8011** Confirm location and condition of all Demo and Exhibition Stock. Confirm stock is separate from regular stock. Confirm stock levels are correct.	Task: 1168 393664 ✓ Marketing Processes Audit :1169 365857 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID **8092** For goods in to book in the returned sensors into the system. Then to chase the returned sensors, and promote our products.	Task: 1288 394660 ✓ Marketing Processes Audit :1289 392013 Managing Director	Freq 1 Risk 1 Overall 1	Task 2W Audit 6W
Audits			
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**
PROCESSID **7721** To carry out Audit 09 Goods Inward And	Task:	Freq 1 Risk 2	Audit 12M

Product Identity Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Audit :170 Company Secretary 391100 + in terms Audit	Overall 2		
PROCESSID **7769** To carry out Audit 09 Goods Inward And Product Identity VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :174 391101 ✓ Company Secretary audit	Freq 1 Risk 2 Overall 2	Audit 12M	
Office Processes				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	Notes
PROCESSID **7792** A report is generated from figures in Intrastats to display how many orders have been shipped without errors	Task: 637 393301 ✓ Managing Director Audit :638 393302 ✓ Company Secretary	Freq 2 Risk 1 Overall 2	Task 3M Audit 3M	
PROCESSID **7914** To download or pdf the proof of deliveries This is not needed at present. It was brought in prior to covid.	Task: 917 370064 ✓ Company Secretary Audit :918 360753 ✓ Office Processes	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
PROCESSID **7943** To review stock levels of 8000004	Task: 1006 393696 ✓ Office Processes Audit :	Freq 1 Risk 1 Overall 1	Task 1M	

Goods In				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	**Notes**
PROCESSID **7859** Checking of the POR Files For Items Delivered But Not Removed From File	Task: 767 394995 ✓ Goods In Audit :	Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7898** Stamp Acceptance of parcels in goods in with date stamp, log entry into the goods in database	Task: 836 395376 ✓ Goods In Audit :	Freq 1 Risk 1 Overall 1	Task 1D	
PROCESSID **7976** Decontamination Of Incomming Products And Repairs. Clean items and make sure safe to handle. Use gloves where needed.	Task: 1098 396656 ✓ Goods In Audit :1099 389019 ✓ Company Secretary	Freq 2 Risk 2 Overall 4	Task 1M Audit 12M	
QA Goods In				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	**Notes**
PROCESSID **7962** To upload any supplier qa results to the PO update log	Task: 1059 393323 ✓ Goods In Audit :1060 382355 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M	
Repair Processes				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	**Notes**
PROCESSID **7897** To check the daily returns for any that are oxygen sensors only, so they can be fast	Task: 834 395375 ✓ Production Processes	Freq 1 Risk 1 Overall 1	Task 1D	

tracked through the system	Audit :		

Rolling Tasks Linked to Document :Task (170) Task (637) Task (174) Task (915) Task (207) Task (231) Task (673) Task (461) Task (727) Task (767) Task (836) Task (878) Task (834) Task (917) Task (921) Task (920) Task (935) Task (1006) Task (1047) Task (1059) Task (1084) Task (1098) Task (1158) Task (1164) Task (1166) Task (1168) Task (1288)