Internal Audit Check list

Viamed Ltd
Handling & Stock Control

Created:	17/May 1995	Audit No 07	
Revised:	09 May 2025		Page 1 of 10
Audit Date	9-May 25	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	Doc index management review QA system Route map
Viamed Ltd ISO13485:2016 6.4.1	**Work environment** The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance; b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person. NOTE Further information can be found in ISO 14644 and ISO 14698	Doc index CPM Training Records HS review Review meetings
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.	Doc index Roles + titles Procedures

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 Renew Route map Barcode tracking
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 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.	Doc index Management Renew Roles + titles Purchasing System
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 Barcode System Procedure
Viamed Ltd ISO13485:2016 7.5.11	**Preservation of product** The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device.	Doc index

	The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).	Procedures Barcode System management review
Viamed Ltd ISO13485:2016 7.5.2	**Cleanliness of product** The organization shall document requirements for cleanliness of product or contamination control of product if: a) product is cleaned by the organization prior to sterilization or its use; b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use; c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; e) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.	Doc index Tech files
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 Tech files Procedures QA system
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 8.2.6	**Monitoring and measurement of product** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures. Evidence of conformity with the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to	Doc index QA system Roles + titles

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	perform measurement activities. Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed. For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.	
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 Intrastat QA System Barcode System Roles + titles
Viamed Ltd ISO13485:2016 8.3.2	**Actions in response to nonconforming product detected before delivery** The organization shall deal with nonconforming product by one or more of the following ways: a) taking action to eliminate the detected nonconformity; b) taking action to preclude its original intended use or application; c) authorizing its use, release or acceptance under concession. The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5).	Roles + titles QA system Barcode tracking procedures.

	QUESTION:	**RESPONSE**	**Y/N**
1	Check all issues from the previous audit are completed.	Nothing outstanding	y
2	Check that incoming products are stored correctly on receipt.		Y
3	Check that the in-house stores area is adequate, safe and accessible.		Y
4	Verify that products for repair are suitably boxed prior to movement. i.e. In ducket with correct paperwork including SRS number.		Y
5	Verify that stock items are suitable packed and		Y

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	labelled for entry into stock.		
6	Check that gloves and or hand sanitiser is available and used, where necessary, when returns are received.		Y
7	Check in Intrastats that COSHH data sheets are available for all products.		Y
8	Check that items in a stock locations are correct to Intrastats. Verify that the quantity of an item in stock is correct to that in Intrastats. Check that the packing and labelling of the finished product is appropriate and will preserve quality to the end user. Check 5 items. ✓ 1. 0110022 2. 8020000 3. 0131202 4. 1114005 5. 2520000		Y
9	Check that demonstration and exhibition stock is separate from other stock, and areas labelled correctly.		Y
10	Verify that product in the non-conforming area can only be removed by authorised personnel. Verify that transfer of non-conformance stock is done by use form QC19.		Y
11	Verify that special requirement areas are available should the product require it.		Y
12	Check that completed products are adequately stored. List those checked. 1. 0110017 2. 8020000 3. 0131202 4. 1114005 5. 2520000		Y
13	Verify that there are adequate storage areas in the workshop for a working stock of assembly components.		Y
14	Check that product movement around the workshop is by ducket only.		Y
15	Are stores and storage areas secure and suitably identified with signs.	all ok.	Y

	List problem areas.		
16	Are uncontrolled material and parts identified as such, and in the correct area. Check that items in Quarantine have HOLD labels with an issue number, date and initials.		Y
17	Check unentered and pre QA items have labels and/or are in the correct area.		Y
18	Are all parts in the warehouse properly identified with Viamed Location Tracking barcodes. Identify unmarked items.		Y

List Processes Per Title

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Product Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7873** Review the Highs and Lows in Temperature of stored stock and products. The temperature range can be found on the temperature page.	Task: 800 362021 ✓ Company Secretary Audit :	Freq 2 Risk 2 Overall 4	Task 3M		
Marketing Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **8024** This is a review of old stock that is being sold and then when stock runs out it will be withdrawn from sale.	Task: 971 364252 ✓ Marketing Processes Audit :1211 363755 + items. Office Processes	Freq 1 Risk 1 Overall 1	Task 1W Audit 12M		
Warehouse Team Leader					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **5858** Opera Counts bulk stock in and issues stock out against orders.	Task: 110	Freq 2 Risk 1 Overall			

Multiple processes cause stock to be used internally, Opera requires a weekly update to bring the stock count into line with whats been used outside the invoicing systems NO LONGER REQUIRED, New system live counts these now	Audit :261		2			
PROCESSID **5935** To allocate stock that has not automatically be linked to a repair or invoice. No longer required with replacement order system	Task: 447 Audit :		Freq 2 Risk 1 Overall 2			
PROCESSID **6850** Review current stock levels	Task: 615 364111 ✓ Goods In Audit :778 361884 ✓ Managing Director		Freq 2 Risk 1 Overall 2	Task 2W Audit 6M		
PROCESSID **6945** To synchronise Opera stock Count against Intrastats internal movement of stock, E.G. Items that wont uniquely appear on an opera order - such as production parts. TASK IS NO LONGER REQUIRED	Task: 110 Audit :783		Freq 1 Risk 1 Overall 1			
PROCESSID **6973** review qc 19 forms	Task: 1170 356390 Managing Director ✓ Audit :		Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID **7673** To check that all the stock on the selves are within their use by dates.	Task: 294 363197 ✓ Goods In Audit :477 361991 ✓ Managing Director		Freq 1 Risk 2 Overall 2	Task 1M Audit 3M		
PROCESSID **7689** Move Stock From QA Shelf To Stock Shelf	Task: 545 364631 ✓ Goods In Audit :		Freq 2 Risk 1 Overall 2	Task 1W		
PROCESSID **7694** Move Stock From QA Shelf To Stock Shelf	Task: 544 364103 ✓ Goods In Audit :782 264203 ✓ Office Processes		Freq 2 Risk 1 Overall 2	Task 1W Audit 12M		
PROCESSID **7695** Move Stock From QA Shelf To Quick Shipping Shelves	Task: 495 364621 x items Goods In Audit :		Freq 1 Risk 1 Overall 1	Task 1W		
PROCESSID **7866**	Task: 785 361431 ✓		Freq 2	Task		

Ensure we do not run out of oxygen	Production Processes Audit :	Risk 1 Overall 2	3M			
PROCESSID **7902** Empty depleted sensor bin from the office	Task: 876 Audit :877	Freq 1 Risk 1 Overall 1				
PROCESSID **7903** Empty Warehouse depleted sensor bin into Bin in cage and record weights in intrastats where relevant	Task: 878 Goods In 363979 Audit :879 3543650 Office Processes	Freq 1 Risk 1 Overall 1	Task 1M Task 3W Audit 6M			
PROCESSID **7904** Check Weeee waste pallet and sensor bin, arrange collection if FULL	Task: 880 3543665 Goods In Audit :881 339742 Office Processes	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M			
PROCESSID **7942** To make sure we have a QA procedure or service manual in place for all our stock coming through Viamed and VST. Some may just say check packaging and barcode and other may need to go further in depth. With testing procedures. Those who do not require testing should state this in the procedure.	Task: 1036 357978 with DL Company Secretary Audit :1037 Managing Director 360200	Freq 1 Risk 3 Overall 3	Task 6M Audit 12M			
PROCESSID **8008** Check sufficient Hand gel and gloves available for use in goods in.	Task: 1162 356381 Office Processes Audit :1163 357164 Production Processes	Freq 1 Risk 1 Overall 1	Task 3M Audit 12M			
Audits						
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes	
PROCESSID **7719** To carry out Audit Audit 07 Handling And Storage Viamed	Task: Audit :25 36524 this Audit Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M			
PROCESSID **7767** To carry out Audit 07 Handling And Storage VST	Task: 361546 This Audit Audit :178 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M			

Goods In

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **8002** Verification goods in products correctly identified	Task: 1149 356233✓ Office Processes Audit :1150 360208✓ Company Secretary	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M		
PROCESSID **8004** Verifiy non conformaing parts and products and segregated identified, with a hold label with an issue number, date and initials on them.	Task: 1153 356234✓ Office Processes Audit :1154 363991✓ Company Secretary	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M		

Production Processes

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **7940** To check the date of the grease used in the production and servicing of the Tom Thumb. To see if it needs to be removed. Look at date purchased then add 4 years to the date. Dispose of this when it goes beyond this date.	Task: 1003 343515✓ Company Secretary Audit :1004 347458✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M		
PROCESSID **7944** To check the use by date or manufacturers life span, of any Sealant, Glues, Greases, Sprays, Gases And Tapes You Use In Production, Service And Repairs For Viamed And VST. To see if it needs to be disposed of. Dispose of and where needed re order new, when it goes beyond this date.	Task: 1011 351562✓ Production Processes Audit :1012 347795✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M		
PROCESSID **8060** To check the use by date or manufacturers life span, of any Sealant, Glues, Greases, Sprays, Gases And Tapes You Use In Production, Service And Repairs For Viamed And VST. To see if it needs to be disposed of. Dispose of and where needed re order new, when it goes beyond this date.	Task: 1010 Production Processes Audit : 360927✓	Freq 1 Risk 1 Overall 1	Task 3M		

Rolling Tasks Linked to Document :Task (25) Task (178) Task (110) Task (447) Task (615) Task (1170) Task (294) Task (545) Task (544) Task (495) Task (785)

Task (800) Task (880) Task (878) Task (876) Task (1036) Task (1003) Task (1011) Task (1162) Task (1149) Task (1153) Task (971) Task (1010)