

Internal Audit Check List
VIAMED LTD
Order Processing Picking Packing & Dispatch

Created	17/May 1995	Audit No 01	
Revised	22 January 2025		Page 1 of 4
Audit Date	22-1-25	Auditor Helen Lamb	350890

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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 procedures Roles + tasks
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	Procedures Doc index Roles + tasks Route map Management review Training record.
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.	Doc index Roles + tasks procedures Route map
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	Doc index procedures

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	<p>production (see 4.2.4);</p> <p>b) qualification of infrastructure;</p> <p>c) implementation of monitoring and measurement of process parameters and product characteristics;</p> <p>d) availability and use of monitoring and measuring equipment;</p> <p>e) implementation of defined operations for labelling and packaging;</p> <p>f) implementation of product release, delivery and post-delivery activities.</p> <p>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.</p>	Management review
Viamed Ltd ISO13485:2016 7.5.11	<p>Preservation of product</p> <p>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. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:</p> <p>a) designing and constructing suitable packaging and shipping containers;</p> <p>b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.</p> <p>If special conditions are required, they shall be controlled and recorded (see 4.2.5).</p>	Barcode tracking management review procedures
Viamed Ltd ISO13485:2016 8.2.4	<p>Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p> <p>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.</p> <p>An audit program shall be planned, taking into consideration</p>	Audit calendar Role map Roles + tasks

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	<p>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.</p> <p>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).</p> <p>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.</p> <p>NOTE Further information can be found in ISO 19011.</p>	Doc index
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Question									
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.								Nothing outstanding. Y
2	Does every Order have official customer paperwork. Check 6 orders at random from the Outstanding Customer Orders list.								Y
Order No.	CID No.	Customer order number	Check attached documents for customer paperwork and associated docs	Does the customer paperwork match the Invoice	Have these the correct goods scanned to them at shipping	Does the account have an email address or other method for invoice delivery	Initials of the person who entered the order	Initials of the person who checked the order	
1 154136	2994	500087025	✓	✓	✓	✓	AM	KG	
2 154005	17049	P0-1637	✓	✓	✓	✓	KG	SL	
3 153809	4794	061524AM	✓	✓	✓	✓	AM	KG	
4 154188	31356	BL028096-1	✓	✓	✓	✓	KG	AM	
5 154175	3867	529563	✓	✓	✓	✓	KG	AM	

No problems seen all seems to be working well

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6 154185	2003	GMPA49 08613-1	✓	✓	✓	✓	KG	AM
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3	Have all Queries been dealt with satisfactorily. Check number of Credit Notes last 6 months and if internal error or customer.	7 internal Goods 24-7-24 onwards 5 customers	Y	No problems
4	Are orders awaiting despatch appropriately packaged and identified.		Y	
5	Is appropriate transport arranged, check goods out.	All going today Nothing sat waiting at time of check	Y	
6	Check Ex-works parcels shipping is arranged.		Y	
7	Check that the appropriate shipping documents are available for the goods in goods out.		Y	
8	Check that the delivery note is attached to the goods.		Y	

List Processes Per Title

Clone from Docid

IT Controller	Process Scope	Roll Task Roll Audit	Risk	Action	* Notes
PROCESSID 8027	To make sure the pricing on the Shopify web shop is updated when the prices are updated in the companies. Regular checks to ensure all prices are correct.	Task: 1204 Marketing Processes Audit :1215 Company Secretary	Freq 1 Risk 1 Overall 1	Task 1W Audit 6M	

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Warehouse Team Leader					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7796 To collate all the franking slips that have errors on them and so where not useable. These are returned to Royal mail for a refund of the carriage.	Task: 645 Goods Out 346371✓ Audit :646 Company Secretary 346991✓	Freq 2 Risk 1 Overall 2	Task 3M Audit 3M		
PROCESSID 7797 Check order are being picked in order of priority and date.	Task: 647 Goods In 349705✓ Audit :648 Managing 346648✓ Director	Freq 2 Risk 1 Overall 2	Task 8W Task 2D Audit 3M		
PROCESSID 7798 Review the orders and items shipped per month	Task: 649 Managing 352271✓ Director Audit :650 Company 346543✓ Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M		
Audits					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7714 To carry out Audit 01 Picking Packing Viamed	Task: Audit :24 Company Secretary 350890✓	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID 7762 To carry out Audit 01 Picking Packing VST	Task: Audit :194 Company Secretary 350896✓	Freq 1 Risk 2 Overall 2	Audit 12M		

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Goods Out					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 5859 audit and snap shot - this is an audit of a part of goods out, listing of the parcels that are sat waiting on a customer response	Task: 105 Goods Out Audit :364 Company Secretary	353109 Freq 2 Risk 1 Overall 2 351237	Task 1W Audit 1M		
PROCESSID 7691 Review the sale or return shelf and ship those items.	Task: 491 Goods Out Audit :353647	353647 Freq 2 Risk 1 Overall 2	Task 1D		
PROCESSID 7860 To pick in order orders from the picking screen package the goods ready for dispatch Invoice out the delivery	Task: Audit :24 Company Secretary	350890 Freq 1 Risk 2 Overall 2	Audit 12M		

Rolling Tasks Linked to Document :Task (24) Task (105) Task (491) Task (645) Task (647) Task (649) Task (1204) Task (194)