Internal Audit Check list			
VIAMED LTD **Order Processing Picking Packing & Dispatch**			
Created	17/May 1995	Audit No 01	
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Audit Date	13-1-26	Auditor Helen Lamb	

	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.	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	Doc index Roles + tasks Route map management review
	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 Roles + tasks purchasing system

		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.	Management Review
	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. 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).	Doc Index Bar code System Management Review 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	Audit Calendar Route Map Robert tasks

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		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.	management review

	Question
1	Review Last years Audit. Update processes if required. Nothing outstanding Are all follow on Issue resolved satisfactory. No Non Conformances.
2	Does every Order have official customer paperwork. Check 6 orders at random from the Outstanding Customer Orders list.

	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	160600	12385	P02099	✓	✓	✓	✓	✓	✓
2	160687	4816	207148	✓	✓	✓	✓	✓	✓
3	160760	2556	RR419217	✓	✓	✓	✓	✓	✓
4	160851	4729	7939	✓	✓	✓	✓	✓	✓
5	160505	4729	7928	✓	✓	✓	✓	✓	✓

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6	160932	2759	240024 290	✓	✓	✓	✓	✓	✓

3	Have all Queries been dealt with satisfactorily. Check number of Credit Notes last 6 months and if internal error or customer. 9 credits our Error + 22 Normal Credits		Y
4	Are orders awaiting despatch appropriately packaged and identified.		Y
5	Is appropriate transport arranged, check goods out.		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

No problems found most of this is System based. We have added systems to reduce errors. No non conformances or problems.

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 385736 ✓ Marketing Processes Audit :1215 371682 ✓ 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 380397 Goods Out Audit :646 380988 Company Secretary	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 381944 Goods In Audit :648 380653 Managing 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 385620 Managing Director Audit :650 380511 Company 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 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 :24 384634 Company Secretary Audit	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7762**	Task:	Freq 1	Audit 12M	

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To carry out Audit 01 Picking Packing 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		Audit :194 Company Secretary 384640 Audit	Risk 2 Overall 2	
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 385702 ✓ Goods Out Audit :364 384919 ✓ Company Secretary		Freq 2 Risk 1 Overall 2	Task 1W Audit 1M	
PROCESSID **7691** Review the sale or return shelf and ship those items.	Task: 491 385851 ✓ Goods Out Audit :		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: 384634 Audit Audit :24 Company Secretary		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)