Internal Audit Check list			
Order Processing Picking Packing & Dispatch			
Created	17/May 1995	Audit No 01	
Revised	27 April 2022		Page 1 of 6
Audit Date	27-4-22	Auditor Helen Lamb	

	Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
	VST Ltd ISO9001:2015 5.1.2	**Customer focus** 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained.	
	VST Ltd ISO9001:2015 8.5.1	**Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error;	

		h) the implementation of release, delivery and post-delivery activities	
	Viamed Ltd ISO13485:2016 6.4.2	**Contamination control** As appropriate, the organization shall plan and document arrangementsfor 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.	Intrastats procedures Doc index
	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	Intrastats Doc index procedure
	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.	Intrastats Doc index Procedure Roles tasks + Audits
	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;	Intrastats Procedures Doc index Roles titles + processes.

		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.	
	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).	Intrastats Doc index Procedure Barcode System management Review
	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	Doc index Audit Calendar Route Map

		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.	

	Question			Yes/ No
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. Are orders stamped signed & dated. Check 6 orders at random.			

	Order No.	Stamped	A/c No.	Initialled and Dated	Checked stamped	Dated and Initialled	Check order confirmation in U drive C company prefix and order number	Check attached documents for customer paperwork and checked docs	Have these the correct goods scanned to them at shipping	Yes/No
	This	is All		digital		Now				
	New		Audit		Being		Written			

3	Have all Queries been dealt with satisfactorily. Check number of Credit Notes last 6 months and if internal error or customer.		Y

4 internal error. 22 credits for named

No ongoing issues.

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

List Processes Per Title

Warehouse Team Leader					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
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.	645 Goods Out 250431 ✓	646 Company Secretary 251164 ✓	Freq 2 Risk 1 Overall 2	Task 3M Audit 3M	
PROCESSID **7797** Check order are being picked in order of priority and date.	647 Goods In 256146 ✓	648 Managing Director 251014	Freq 4 Risk 1 Overall 4	Task 8W Task 2D Audit 3M	
PROCESSID **7798** Review the orders and items shipped per month	649 Managing Director 256934 ✓	650 Company Secretary 250893 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
PROCESSID **7825** To Pick and Pack customer Orders			Freq 1 Risk 1 Overall 1		
Audits					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues

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PROCESSID **7714** To carry out Audit 01 Picking Packing Viamed		24 Company Secretary 246766 ✗	Freq 1 Risk 2 Overall 2	Audit 12M	This Audit
PROCESSID **7762** To carry out Audit 01 Picking Packing VST		194 Company Secretary 246776 ✗	Freq 1 Risk 2 Overall 2	Audit 12M	
Goods Out					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
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	105 Goods Out 258282 ✗ in terms.	364 Company Secretary 256100 ✓	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **7691** Review the sale or return shelf and ship those items.	491 Goods Out 258442 ✓		Freq 3 Risk 1 Overall 3	Task 1D	
PROCESSID **7860** To pick in order orders from the picking screen package the goods ready for dispatch Invoice out the delivery		24 Company Secretary 246766 ✗	Freq 1 Risk 2 Overall 2	Audit 12M	