VST

Internal Audit Check list

GOODS INWARDS & PRODUCT IDENTITY

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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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	Doc Index Procedure Tech files QA System Renew meetings calibration Index Roles + Titles PMS Feedback.
VST Ltd ISO9001:2015 8.5.2	**Identification and traceability** The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.	QA System Procedures Barcode Tracking Doc Index
VST Ltd	**Property belonging to customers or external providers**	

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ISO9001:2015 8.5.3	The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred. NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.	QA System Procedures Doc index Barcode tracking
VST Ltd ISO9001:2015 8.5.4	**Preservation** The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.	QA System Procedures Barcode Tracking Doc index
VST Ltd ISO9001:2015 8.6	**Release of products and services** The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release	Doc index management Review marketing index
VST Ltd ISO9001:2015 8.7.1	The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways:	QA System Barcode tracking Procedures PMS Feedback Doc index

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	a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.	*S mlie Revica*
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	✓
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.	✓
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.	
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).	
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;	

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	b) requirements for product acceptance, procedures, processes and equipment; c) requirements for qualification of supplier personnel; 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).	
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).	
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;	

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	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 7.5.10	**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).	/
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.	/
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.	/

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	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 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)	/

V S T

	QUESTION:	RESPONSE:	Y/N
1	Check all issues from the previous audit are completed.	Nothing out standing	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

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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. 2. 3. 4. 5.	No Items on QA shelf Sensors not QA'ed		
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.	Nothing 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.	Nothing 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. PST 2927 ✓ 2. PST 2929 ✓ 3. PST 2866 ✓ 4. PST 2951 ✓			Y

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	5. PST 3020 ✓ for VST we only Receive deliveries from Honeywell Enitec		Y
8	Check that items, once through QA are packaged correctly and labelled appropriately. List 5 checked. 1. 2. 3. 4. 5. checked 8010006 as they are only ones in		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.	all processed	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.		Y
11	Check that the relevant information is entered onto Intrastats. Check 5 SRS's. Returns – Returns Completed or Repairs not completed. 1. 68403 ✓ missing email address 2. 68374 ✓ 3. 68351 ✓ 4. 68343 ✓ missing email address. 5. 68315 ✓	issue 292109 Sent to DL	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.	Nothing Unidentified.	Y
13	Are goods identified Hold when awaiting action and in the appropriate area. HOLD label must have Issue Number,		Y

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	date and initials. List any items that are unidentified.		
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.	Task uphodate No issues	Y
15	Check that there are no goods over one month left waiting to be returned on the shelf.		Y
16	Check Meeting in Intrastats is completed quarterly by MD.		Y
17	Check that completed stock is identified as such by Barcodes and the location is correct. Check 5 stock items at random. 1. 8010006 ✓ censors ← opl, sellable ✓ 2. 8000004 cables Stock. 3. 8050040 labels not Stock Item 4. 8010000 sensors samples 5.		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

Managing Director					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Referenced in Document
PROCESSID **7830** To review the Quantities of Failed product per Stock reference Passing through the Q.A. system	727 Goods In	729 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

IT Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **6838** To find and correct opera when it reads Negative stock values. NOT REQUIRED ANYMORE Opera	461		Freq 1 Risk 1 Overall 1		

Product Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **5854** To update and maintain the Stock FAQ list	231 Director 3 (Steve) *288063*	374 Managing Director *284131*	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M	

Marketing Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **6894** Maintenance and research of cross reference tables	673 Marketing Processes *289921*	674 Director 3 (Steve) *28167*	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

Sales Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **57** To Review Memos on Stock references tagged as Temporary	207 Director 3 (Steve) *289144 X*	206 Managing Director *287924*	Freq 2 Risk 1 Overall 2	Task 1M Audit 3M	

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced

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					in Document
PROCESSID **7826** To Receive Goods from Suppliers	915 Goods Out ⟲ ✓ 28782 ✓	734 Office Processes 28161 ✓	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	878 Goods In 29030 ✓	879 Office Processes 28527 ✓	Freq 1 Risk 1 Overall 1	Task 1M Task 3W Audit 6M	
PROCESSID **7914** To download or pdf the proof of deliveries	917 Company Secretary 4✓ 28978 ✓	918 Office Processes 28917 ✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M	
PROCESSID **7915** To ensure we have enough items of particular stock for certain customer whom can and do place large orders of regular stock,	921 Goods In 29027 ✓		Freq 1 Risk 1 Overall 1	Task 1W	
PROCESSID **7917** Check stock requirements for human med Stock NO Longer required	920		Freq 1 Risk 1 Overall 1		
PROCESSID **7923** To Review and tidy up any outstanding RMAs that have been resolved by Supplier credit notes	935 Goods Out 28950 ✓	936 Goods In 28803 ✓	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 with a production Job	1047 Director 3 (Steve) 28973 X		Freq 1 Risk 1 Overall 1	Task 1M	
PROCESSID **7967** To count the final year end stock for VST	1084 Goods In 28918		Freq 2 Risk 2 Overall 4	Task 12M	
PROCESSID **8006** Visually check the warehouse for unidentifed stock	1158 Company Secretary ✓ 28828S	1159 Managing Director ✓ 28811	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **8009** Randomly test/list 5 stock Items from	1164 Office	1165 Production	Freq 1 Risk 1	Task 6M Audit	

203034 ✓   284736 ✓

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Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
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.	Processes	Processes	Overall 1	12M	
PROCESSID **8010** Verify Ebay stock is scanned to the correct shelf.	1166 Marketing Processes 264934 ✓	1167 Office Processes 25520 ✓	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.	1168 Marketing Processes 284984 ✓	1169 Managing Director 256165 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7721** To carry out Audit 09 Goods Inward And Product Identity Viamed	viamed Audit 288860	170 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7769** To carry out Audit 09 Goods Inward And Product Identity VST	This Audit 288861	174 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7792** A report is generated from figures in Intrastats to display how many orders have been shipped without errors	637 Managing Director 282027 ✓	638 Company Secretary 281997 ✓	Freq 2 Risk 1 Overall 2	Task 3M Audit 3M	
PROCESSID **7914** To download or pdf the proof of deliveries	917 Company Secretary 289798 ✓	918 Office Processes 289191 ✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M	

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PROCESSID **7943** To review stock levels of 8000004	1006 Office Processes _288651_		Freq 1 Risk 1 Overall 1	Task 1M	

Goods In

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7859** Checking of the POR Files For Items Delivered But Not Removed From File	767 Goods In _289919_		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	836 Goods In _290307_		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.	1098 Goods In _289499_	1099 Company Secretary _286619_	Freq 2 Risk 2 Overall 4	Task 1M Audit 12M	

QA Goods In

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7962** To upload any supplier qa results to the PO update log	1059 Goods In _288111_	1060 Managing Director _279467_	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M	

Repair Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7897** To check the daily returns for any that are oxygen sensors only, so they can be fast tracked through the system	834 Production Processes _290281_		Freq 1 Risk 1 Overall 1	Task 1D	

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