Internal Audit Check list			
GOODS INWARDS & PRODUCT IDENTITY			
Created:	17/May 1995	**Audit No 09**	VM3/COP05/06 VOP07
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Audit Date		Auditor	

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	
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.	
VST Ltd ISO9001:2015 8.5.3	**Property belonging to customers or external providers** 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.
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.
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
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: 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.

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;

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;

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).

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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.

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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 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)

	QUESTION:	**RESPONSE:**	**Y/ N**
1	Check that stock booked in is transferred to relevant location with Barcodes.		

2	Verify that goods are checked against the original Purchase Order and Supplier delivery Note and then entered into the Goods-in Book in intrastats. Check the Supplier delivery Note has been stamped with the Opera Received stamp and been dated 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 POR and go to the Delivery Notes file. 1 2 3 4 5		
3	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 and Issue Number. List any that are unidentified.		
4	Are goods identified Hold when awaiting action and the appropriate area. List any items that are unidentified.		
5	Check the Goods in Book on Intrastats has been filled in correctly. Look at the last week. In Stock – Deliveries		
6	Are all incoming consignments logged in the Goods Inward Book on intrastats. Check 5 random Delivery Notes/POR`s for the previous 3 months from different companies. 1 2 3 4 5		

7	Check that items, once through QA are packaged correctly and labelled appropriately. List 5 checked. 1 2 3 4 5		
8	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.		
9	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.		
10	Check that the relevant information is entered onto Intrastats. Check 5 SRS's. Returns – Returns Completed or Repairs not completed. 1 2 3 4 5		
11	Check the building for unidentified or unmarked goods with out a hold label. The label should include an Issue number. List any that are found.		
12	Are goods identified Hold when awaiting action and the appropriate area. List any items that are unidentified.		
13	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.		

14	Check that there are no goods over one month left waiting to be returned on the shelf.		
15	Check Meeting in Intrastats is completed monthly by MD.		
16	Check that completed stock is identified as such by Barcodes and the location is correct. Check 5 stock items at random. 1 2 3 4 5		
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.		

Sub Processes Linked to Audit 09

Review the below processes tasks and audits and ensure they are completed in a timely manner.

Managing Director

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
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**	Notes / Issues
PROCESSID **6838**	461		Freq 1	Task	

To find and correct opera when it reads Negative stock values.	Managing Director		Risk 1 Overall 1	12M

Marketing Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **6894** Maintenance and research of cross reference tables	673 Marketing Processes	674 Director 3 (Steve)	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

Product Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **5854** To update and maintain the Stock FAQ list	231 Director 3 (Steve)	374 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

Sales Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **57** To Review Memos on Stock references tagged as Temporary	207 Director 3 (Steve)	206 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7826** To Receive Goods from Suppliers		734 Managing Director	Freq 2 Risk 2 Overall 4	Audit 3M	

Goods In

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7859** Checking of the POR	767 Goods In		Freq 3 Risk 1	Task 1M	

Files For Items Delivered But Not Removed From File	Overall 3

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7721** To carry out Audit 09 Goods Inward And Product Identity Viamed		170 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7769** To carry out Audit 09 Goods Inward And Product Identity VST		174 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7792** A report is generated from figures in Intrastats to display how many orders have been shipped without errors	637 Office Processes	638 Managing Director	Freq 2 Risk 1 Overall 2	Task 3M Audit 3M	