Viamed + VST

Internal Audit Check list			
GOODS INWARDS & PRODUCT IDENTITY			
Created:	17/May 1995	**Audit No 09**	VM3/COP05/06 VOP07
Revised:	15 June 2018		Page 1 of 12
Audit Date	22-3-19	Auditor Helen Lamb	

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	Procedures Intrastats Procedures + QA Regular Review + Audit QA + Intrastats Audit + Reviews Training + Intrastats QA, Roles + Resp. Review Meetings Intrastats Intrastats
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 Intrastats
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.

Audit + Intrastats

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 + Intrastats

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

Intrastats - Jobs list Project list

intrastats

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;

intrastats

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.

infrastruk + procedures. Rolling tasks to monitor

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

Audit + Review meeting including H+S Review and Regular meetings + Report issues.

QA + 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

Viamed have No steril products

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).

Intruskits. Jobs list. + Project list

In planning product realization, the organization shall

determine the following, as appropriate: Jcb and projects list
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; Jcbs + project list
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; QA + proceedures
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). Projects + jobs list QA + procedures
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; Intrastats
b) based on the performance of the supplier; supplier review
c) based on the effect of the purchased product on the quality of the medical device; supplier Review + Intrastats
d) proportionate to the risk associated with the medical device. post market Survalance Intrastats
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; Opera purchase order

b) requirements for product acceptance, procedures, processes and equipment; Intrastats, Open + T+Cs
c) requirements for qualification of supplier personnel; Supplier review
d) quality management system requirements. Supplier Review
The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. Intrastats + Reporting of issues
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. through Intrastats.
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. QA
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. Issues and Intrastats, Review
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). Intrastats Issues and Doc index

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); QA and Intrastats
b) qualification of infrastructure; Review meetings
c) implementation of monitoring and measurement of process parameters and product characteristics; QA and procedures
d) availability and use of monitoring and measuring equipment; Review meetings
e) implementation of defined operations for labelling and packaging;
Intrastats procedures

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.

Jobs and project list, post market surveilance, + intrastats

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).

Procedures intrastats + QA

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.

intrastats.

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

intrastats Rolling tasks.

Renew meetings

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.

audit Review meetings

issues intrastats

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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)

intrastats + QA

issues + meetings

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

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 ID 1350246 R22AV POR12106 ✓ loc Del Note ✓ 2 1353174 MD300C2 POR12175 ✓ ✓ 3 1352495 0014850 POR11918 ✓ ✓ not fully Del. 4 1349813 R22Medv POR12122 ✓ ✓ 5 1353640 MD300C15D POR12175 ✓ ✓ viamed. Nothing awaiting QA for VST		Y
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.	none at time of audit	Y
4	Are goods identified Hold when awaiting action and the appropriate area. List any items that are unidentified. 2 duchets found and sorted.	#143134 issue sent to everyone everything needs a hold label and issue.	NO
5	Check the Goods in Book on Intrastats has been filled in correctly. Look at the last week. In Stock – Deliveries		Y
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 POR12202 omni sensors ✓ 2 POR12177 Posen ✓ 3 POR12176 maxtec ✓ Labelled incorrectly POR1175 4 POR12164 Envtec ✓ POR12081 Dup order booked in under new AR 5 POR 12135 Maxtec ✓ Viamed VSTA000 1 930 Envtec ✓ 2 927 Envtec ✓ 3 916 Envtec ✓ 4 912 Envtec ✓ 5 903 Envtec ✓ VST		Y

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7	Check that items, once through QA are packaged correctly and labelled appropriately. List 5 checked. 1 ID 1352980 ✓ ID135833 ✓ 2 ID 1216499 ✓ ID 135882 ✓ 3 ID 1307358 ✓ ID 1229352 ✓ 4 ID 1102298 ✓ ID 1351732 ✓ 5 ID 1288562 ✓ Viewed VST	components. components	Y
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.		Y
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.		Y
10	Check that the relevant information is entered onto Intrastats. Check 5 SRS's. Returns – Returns Completed or Repairs not completed. 1 SRS 66984 ✓ SRS 66988 No email 2 SRS 66993 ✓ SRS66913 No A/C No. or tel. No. 3 SRS 66947 ✓ SRS 67007 4 SRS 66950 No phone Number - expect through 5 SRS 67020 ✓ SRS 66985 ✓ Viamed SRS 66969 ✓ VST		Y
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.	Sample sensors Issue Sent #143134	
12	Are goods identified Hold when awaiting action and the appropriate area. List any items that are unidentified.	none	Y
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.	#142938 ✓	Y

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14	Check that there are no goods over one month left waiting to be returned on the shelf.	only problem - teledyne waiting on responses + decission on Credit or Return	Y
15	Check Meeting in Intrastats is completed monthly by MD.	#143157 Not sure what meeting I need to review	
16	Check that completed stock is identified as such by Barcodes and the location is correct. Check 5 stock items at random. 1 1327363 - 34289 ✓ 2 986105 - 837988 ✓ 3 1103815 - 837850 ✗ 4 683373 - 83788 ✓ 5 1332667 - 838087 ✓ Viamed VST	1353833-126537 ✓ But whole block is Negmask #143155 (overflow shelf) ✓	Y ✓ #143319 ✓ 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.

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	#139468 727 Goods In	#131363 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 #133882		Freq 1	Task	

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

Marketing Controller

27.Dec 18 Audit next are due 26 March 19

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **6894** Maintenance and research of cross reference tables	#140569 ✓ 673 Marketing Processes	#134951 X 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	#139344 ✓ 231 Director 3 (Steve)	#136494 ✓ 374 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

Sales Controller

within terms

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **57** To Review Memos on Stock references tagged as Temporary	#140092 X 207 Director 3 (Steve)	#139261 ✓ 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		#134957 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	#140490 767 Goods In		Freq 3 Risk 1	Task 1M	

Files For Items Delivered But Not Removed From File — Overall 3

Audits

This Audit

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7721** To carry out Audit 09 Goods Inward And Product Identity Viamed	#139994	170 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7769** To carry out Audit 09 Goods Inward And Product Identity VST	#139996	174 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	This Audit

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	#135188 637 Office Processes	#135161 638 Managing Director	Freq 2 Risk 1 Overall 2	Task 3M Audit 3M	