Vlamed Ltd + VST Ltd.

Internal Audit Check list

Calibration Index

Created:	17/May 1995	**Audit No 6**	VM3/COP11 VOP11
Revised:	13 July 2020		Page 1 of 5
Audit Date	3 Sept 20	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments Issues
VST Ltd ISO9001:2015 7.1.5.1	**General** 7.1.5.1 General The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continuing fitness for their purpose. The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.	QA Intrastats management Review Doc relet
VST Ltd ISO9001:2015 7.1.5.2	**Measurement traceability** When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine their status; c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary	Calibration index Intrastats Doc index
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,	Doc index Intrastats Intrastats/QA

	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
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.	Doc index Intranets Calibration index + management Review
Viamed Ltd ISO13485: 2016 7.6	**Control of monitoring and measuring equipment** The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5); b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5);	Calibration index Intranets Doc index

	c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.5). The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). NOTE Further information can be found in ISO 10012.	Procedures Rder + Response task audit system
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 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	audit calendar internals issues Doc update

	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 8.5.1	**General** The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post market surveillance, analysis of data, corrective actions, preventive actions and management review.	

due to Covid 19 there have been some delays in processing Calibration index now being done.

Calibration register has been transferred to Intrastats. Out of calibration test equipment automatically flags when it is requested for use.

Role ID 80

	QUESTION:	RESPONSE	Y/N
1	Check all issues from the previous audit are completed. nothing outstanding		Y
2	Verify the existence of a calibration register and associated issues in Intrastats	Done in Intrastats	N/Y
3	Is the register maintained. This can be found on Intrastats in ISO – Calibration Index		Y
4	Check QA, R + D Room, Workshop etc. for equipment that does not have a Viamed Bar Code CE sticker. #196705 Covid 19 Asheel RC to check as independent		
5	Is equipment calibrated within its due period Some delays due to Covid 19	Done in Intrastats	Y
6	Verify that records show any measurements taken and parameters stated.	Done in Intrastats	Y
7	Is the register updated with this information.	Done in Intrastats	Y

Issue - doc Notes Attached.

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8	Verify that where items which failed calibration are assessed to ascertain potential recall of product. VOP 06	None failed calibration	Y
9	Are Calibrations traceable to UKAS Standards. CE206 - CE076 - #146134 ✓		Y
10	Are In-House calibration procedures listed in the Intrastats Document Index where required.	Doc id 15166 for CE206 ✓	Y

Sub Processes Linked to Audit 06

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

List Processes Per Title

Warehouse Team Leader					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7048** Control of monitoring and measuring devices	547 Production Processes #195699	in terms	Freq 3 Risk 2 Overall 6	Task 1M	
PROCESSID **7091** To ensure that all equipment that requires calibration is done. In the correct timescale and manor.	547 Production Processes #195699 in terms	80 Managing Director #195986.	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
Audits					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7718** To carry out Audit 06 Calibration Viamed		20 #184653 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7766** To carry out Audit 06 Calibration VST		182 #184656 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	