Internal Audit Check list

VIAMED LTD

CALIBRATION INDEX

Created:	17/May 1995	**Audit No 6**	
Revised:	30 May 2025		Page 1 of 5
Audit Date	30-5-25	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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 Rolles + task management Renew Purchasing system
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); 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	Calibration index Doc index Barcode System Procedures

Internal Audit Check list

VIAMED LTD

CALIBRATION INDEX

Created:	17/May 1995	**Audit No 6**	
Revised:	30 May 2025		Page 2 of 5
Audit Date		Auditor	

	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.	
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 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	Route map Audit calendar Doc index Roles + tasks

Internal Audit Check list

VIAMED LTD

CALIBRATION INDEX

Created:	17/May 1995	**Audit No 6**	
Revised:	30 May 2025		Page 3 of 5
Audit Date		Auditor	

	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.	management Renew issues> meetings

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 no Non con issues.		Y
2	Verify the existence of a calibration register and associated issues in Intrastats		Y
3	Is the register maintained. This can be found on Intrastats in ISO – Calibration Index Task id - 547	363229	Y
4	Check QA, R and D Room, Workshop etc. for equipment that does not have an in house calibration barcode CE sticker. Send an issue to engineering staff and other warehouse staff to check their areas for unlabelled calibration test equipment. Issue Sent 365729	issue sent.	Y

Internal Audit Check list

VIAMED LTD

CALIBRATION INDEX

Created:	17/May 1995	**Audit No 6**	
Revised:	30 May 2025		Page 4 of 5
Audit Date		Auditor	

5	Check calibrated test equipment for a date sticker. Check 5 calibrated test equipment dates match to those in the Calibration Index. Check each piece of equipment has a date calibrated sticker attached 1. CE112 ✓ 2. CE0185 ✓ 3. CE149 ✓ 4. CE210 ✓ 5. CE22 ✓ Says in System # 367474 to PC + HL	Do need more indication only labels	Y
6	Is equipment calibrated within its due period		Y
7	Verify that records show any measurements taken and parameters stated.		Y
8	Is the register updated with this information.		Y
9	Verify that where items which failed calibration are assessed to ascertain potential recall of product.		Y
10	Are Calibrations traceable to UKAS Standards.		Y
11	Are In-House calibration procedures listed in the Intrastats Document Index where required.		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	547 Production 363229 ✓		Freq 3 Risk 2	Task 1M	

Internal Audit Check list

VIAMED LTD

CALIBRATION INDEX

Created:	17/May 1995	**Audit No 6**	
Revised:	30 May 2025		Page 5 of 5
Audit Date		Auditor	

measuring devices	Processes		Overall 6		
PROCESSID **7091** To ensure that all equipment that requires calibration is done. In the correct timescale and manor.	547 Production Processes 363229 / 357765	80 Managing Director	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
Audits	This Audit				
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7718** To carry out Audit 06 Calibration Viamed	364782	20 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7766** To carry out Audit 06 Calibration VST	364785	182 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

This Audit