Internal Audit Check list

VIAMED LTD PRODUCTION

Created:	17/May 1995	**Audit No 15**	VOP 08
Revised:	21 July 2025		Page 1 of 5
Audit Date	21-7-25	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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	Doc index management Review HS Review 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.	Procedures Doc index Roles + titles Purchasing 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	Audit Calendar Route Map Roles + titles management review

	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 8.2.6	**Monitoring and measurement of product** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures. Evidence of conformity with the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities. Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed. For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.	QA system procedures Rdes + titles

	QUESTION:	**RESPONSE**	**Y/N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	nothing outstanding *	Y
2	Check that each job for production has its own unique worksheet in the ducket.		Y
3	Does the worksheet contain all the relevant information.		Y
4	Check that all jobs are kept in an appropriate duckets.		Y
5	Check that jobs awaiting assembly are in the correct area.	Production jobs are usually released one at a time. These are worked on at time of release.	Y
6	Verify that all parts are correctly scanned to the production build by the operator. Use the PS production number from a production job in a ducket or from the all jobs list and then put it into -		

No non conformance issues.

	Production – Parts pick. This list can then be compared to the stock procedure – Parts List to Build batch. Check 5 to see if what is scanned matches what is required. 1. PRO 3817 - 0110239 2. PRO 3814 - 0110224 3. PRO 3816 - 1410000 4. PRO 3812 - 1410000 5. PRO 3782 - 1410000		Y
7	Check that the operating procedure is with the job, and is the latest issue.	Intrastats links to production COPS	N/A
8	Verify that the operator has adequate training and / or experience.	Training Audit	N/A
9	Verify that there is adequate tooling to complete the task.		Y
10	Check that completed jobs are in the correct area.		Y
11	Verify that all the relevant information is entered into Intrastats. Check 5 production jobs. Use the same as above to find a barcode ID from each Production job and check its QA history. 1. PRO 3817 - 0110239 - No QA re 2. PRO 3814 - 0110224 - No QA re 3. PRO 3816 - 1410000 - in process 4. PRO 3812 - 1410000 - ✓ 5. PRO 3782 - 1410000 - ✓	labelling - labelling - too recent ✓	Y
12	Check the Start Job List in Production to see if they are all valid. Review any older than a month. List any below.	PRO 3757 - 0110073 from March. Issue sent to CG. 370409	N
13	Check the Production in Production List, in production. The list shows what is in and at what stage it is at. Review any older than a month. List any below.	PRO 3718 - Sent for EMC testing Pending - Issue to DL 370410 sent	N
14	Check that finished product is placed in the correct area for test.	Tested at time of production	Y
15	Is there adequate storage and working facilities.		Y
16	Is the production area in a tidy and workable state.		Y

17	Can resources be improved to facilitate process control.		2

List Processes Per Title

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Health And Safety Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **8037** To check to see if products have changes or if there are any new products. Are there any new HSE implications.	Task: 54 346504✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
Warehouse Team Leader					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **6955** To set production job for any stock item that is needed for customer back order, warehouse requests or marketing	Task: 907 370309 Director 3 (Steve) + items Audit :908 363749✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 1W Audit 3M		
Audits					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7727** To carry out Audit 15 Production Viamed Audit	Task: Audit :28 362949+ Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID **7775** To carry out Audit 15 Production VST audit	Task: Audit :175 362955+ Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
Production Processes					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7736** When a new production is needed we the production job to the list of procedures.	Task: 553 369057✓ Goods Out Audit :554 368743✓	Freq 2 Risk 2 Overall 4	Task 1M Audit 3M		

Check to make sure that every new job has a procedure linked to it.	Managing Director					
PROCESSID **7737** Review the Production List, check and list those items that were started more than 30 days ago have not been through QA. Audit is carried out and production is reviewed and chased at this point.	Task: 556 368474 ✓ Managing Director Audit :557 368475 ✓ Company Secretary	Freq 2 Risk 2 Overall 4	Task 1M Audit 3M			
PROCESSID **7738** Production Review, Identify any production jobs taking a long amount of time	Task: 551 369056 ✓ Managing Director Audit :552 368742 ✓ Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M			
PROCESSID **8000** Verifiy all production jobs have correct paperwork in the ducket with the production job	Task: 1145 355070 ✓ Goods In Audit :1146 360201 ✓ Managing Director	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M			
PROCESSID **8064** Production of JJCCR Cables	Task: 1199 369712 ✓ Goods Out Audit :	Freq 1 Risk 1 Overall 1	Task 2W			

Rolling Tasks Linked to Document :Task (28) Task (553) Task (556) Task (551) Task (175) Task (907) Task (1145) Task (54) Task (1199)