Internal Audit Check list			
VIAMED LTD PRODUCTION			
Created:	17/May 1995	**Audit No 15**	VOP 08
Revised:	22 May 2026		Page 1 of 6
Audit Date	26-5-26	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 QA systems Route map
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 Roles + titles procedures 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 + tasks

	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 Roles and tasks procedures.

	QUESTION:	**RESPONSE**	**Y/N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory. No Non	No issues outstanding conformances	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 -		

	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. PS3939 0110248 2. PS3935 0012167 3. PS3933 0110239 4. PS 3946 0012167 5. PS 3942 8000004 Where appropriate stock Scanned.	we do not do medical production. This is all VST/Van Labelling work.	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. PS3939 0110248 - Label 2. PS3935 0012167 3. PS3933 0110239 - Labelling 4. PS3946 0012167 5. PS3942 8000004 - cables for VST		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. Vandagraph one 2025 Dec.	all valid No Named Issues	Y
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.	all newer than 1 month.	Y
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.		N

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 380483 ✓ 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 398168 Director 3 (Steve) in forms Audit :908 396788 ✓ 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 Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.	Task: 396118 ✗ Audit Audit :28 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.				
PROCESSID **7775** To carry out Audit 15 Production VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :175 Company Secretary 396124 Audit	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. Check to make sure that every new job has a procedure linked to it.	Task: 553 396388 ✓ Goods Out Audit :554 393531 ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 1M Audit 3M	
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 396156 ✓ Managing Director Audit :557 393291 ✓ 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 396387 ✓ Managing Director ✓ Audit :552 393530 ✓ 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 Goods In 388337 ✓ Audit :1146 393525 ✓ Managing Director	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M	
PROCESSID **8064** Production of JJCCR Cables	Task: 1199 Goods Out 397562 ✓ 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)