Internal Audit Check list

Viamed Ltd Technical Files

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Audit Date	27/3/25	Auditor Helen Lamb	ISO

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 7.3.1	**General** The organization shall document procedures for design and development	Doc index Tech files marketing
Viamed Ltd ISO13485:2016 7.3.10	**Design and development files** The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.	Tech files marketing index Doc index
Viamed Ltd ISO13485:2016 7.3.2	**Design and development planning** The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development; e) the methods to ensure traceability of design and development outputs to design and development inputs; f) the resources needed including necessary competence of personnel	Tech files Doc index marketing index
Viamed Ltd ISO13485:2016 7.3.3	**Design and development inputs** Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include: a) functional, performance, usability and safety requirements, according to the intended use; b) applicable regulatory requirements and standards; c) applicable output(s) of risk management; d) as appropriate, information derived from previous similar designs; e) other requirements essential for design and development of the product and processes. These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other. NOTE Further information can be found in IEC 62366–1.	QA System Doc index Route map Roles + titles Review meetings
Viamed Ltd ISO13485:20	**Design and development outputs** Design and development outputs shall:	

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16 7.3.4	a) meet the input requirements for design and development; b) provide appropriate information for purchasing, production and service provision; c) contain or reference product acceptance criteria; d) specify the characteristics of the product that are essential for its safe and proper use. The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release. Records of the design and development outputs shall be maintained (see 4.2.5).	Tech files Doc index Review meetings
Viamed Ltd ISO13485:2016 7.3.5	**Design and development review**	Tech files Doc index QA. Review meetings
Viamed Ltd ISO13485:2016 7.3.6	**Design and development verification** Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements. The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5).	Tech files Doc index management Review QA System
Viamed Ltd ISO13485:2016 7.3.7	**Design and development validation** Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. The organization shall document validation plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size. Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5).	Tech files Doc index Procedures Roles + titles.

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	As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. Validation shall be completed prior to release for use of the product to the customer. Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5).	
Viamed Ltd ISO13485:2016 7.3.8	**Design and development transfer** The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded (see 4.2.5).	Tech files Doc index Procedures
Viamed Ltd ISO13485:2016 7.3.9	**Control of design and development changes** The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified. Before implementation, the changes shall be: a) reviewed; b) verified; c) validated, as appropriate; d) approved. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes. Records of changes, their review and any necessary actions shall be maintained (see 4.2.5).	management Renew Tech files Doc Index

Paper files are becoming obsolete as electronic documentation supersedes them.
All CE Technical files should be in Intrastats Document Index.

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Emails can be found in Gmail, Goldmine and documentation in Intrastats.

	Question	Comments	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory. No Non conformances arising from last	Nothing outstanding	Y
2	Check the list of current CE Files in Intrastats. Do all our products have a CE File. Review list and see if any are missing. ISO – Tech Files, top dark blue section ad the light blue OBL below. close to end of 7 years.	Viamed no longer has any products old file still renewed.	Y
3	Check Cross reference in Intrastats – Family Types. ISO – Tech Files Are all the Products present review	No products no longer monitored	Y
4	Check that all Viamed Products (dark blue at the top) are Green for PMS – Post market surveillance. List those not and Issue to technical manager. Last production without incident.	products now being removed for renew. over 7 years since	Y
5	Check that all Viamed Products and OBL's (dark blue and light blue the top two sections) are blue for Risk assessment. List those not and Issue to technical manager.	No OBL's No products.	Y
6	Do all files contain the Basic information required. Are there any Red areas. Cross reference. ISO – Tech files – second icon Cross ref families and files/regulations – ISO BSI Required – Viamed Products – Submit. Speak to quality controller and ask if there are any problem areas, the system is highly complex and understanding of this is not required by auditor.	No Viamed products no longer monitored.	N/A
7	Are MDA guidelines are available for classification information. In ISO- Tech Files	This is an Intrastats automatic process when developing a new product.	Y

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8	Check that ONLINE Registration Protocol has been completed and submitted to MDA for any Class I products. ISO Tech Files, the bracketed number is the CE classification. This is in the check list for when we develop a new Viamed product.	Check the (1)'s and see if they have the MDA letter present.	N/A
9	Check the Canadian Medical Devices CMDCAS form is filled in annually. ISO – Tech Files (At present the microstims are our only products that we sell to Canada)	We No Longer CMDCAS. Can ignore this question for now	N/A
10	Pick one of our Files in the ISO – Tech Files Dark Blue and answer the following		
11	Have there been any product changes since the last Audit		N/A
12	Have Risk assessments been completed on change		N/A
13	Have there been any classification changes		N/A
14	Any new accessories.		N/A
15	Any label changes		N/A
16	Any User information changes		N/A
17	Any sales leaflet changes		N/A
18	Any Data sheet changes		N/A
19	Any maintenance or service manual changes		N/A
20	Any other major changes effecting CE Files		N/A

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

List Processes Per Title

Clone from Docid

ISO Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7071** The process by which re view and risk assess all product files, check that no Products / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.	Task: 50 354298 Managing Director Audit :14 327856 Company Secretary	Freq 1 Risk 3 Overall 3	Task 2M Audit 12M		

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PROCESSID **7172** Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.	Task: 50 3542984 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 2M		
Audits					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7725** To carry out Audit 12 CE Files Viamed	Task: 359360 Audit :16 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID **7773** To carry out Audit 12 CE Files VST	Task: 359361 Audit :176 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		

Rolling Tasks Linked to Document :Task (16) Task (176) Task (50)