VST

Internal Audit Check list			
Technical Files			
Created:	17/May 1995	**Audit No 12**	
Revised:	15 May 2024		Page 1 of 9
Audit Date	1/5/24	Auditor Helen Lamb	ISO

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 10.2.1	When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Procedures Complaints Doc index Roles + titles Review meetings Route map
VST Ltd ISO9001:2015 6.1.2	The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.	Risk assessments. Renew Risk External parties management renew
VST Ltd ISO9001:2015 7.1.6	**Organizational knowledge** The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider	experienced members of staff Doc index

	its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)	PMS Feedback Supplier Review
VST Ltd ISO9001:2015 7.5.3.2	For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use; b) storage and preservation, including preservation of legibility; c) control of changes (e.g. version control); d) retention and disposition. Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations. NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.	Doc Index Required Reading operating procedures tech files
VST Ltd ISO9001:2015 8.2.2	**Determining the requirements for products and services** When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers.	Doc index Route map marketing index + Review
VST Ltd ISO9001:2015 8.3.2	**Design and development planning** In determining the stages and controls for design and development, the organization shall consider: a) the nature, duration and complexity of the design and development activities;	management Review tech files

	b) the required process stages, including applicable design and development reviews; c) the required design and development verification and validation activities; d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process by customers and other relevant interested parties; j) the documented information needed to demonstrate that design and development requirements have been met.	Doc index marketing index + Renew
VST Ltd ISO9001:2015 8.3.3	**Design and development inputs** The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs.	Renew meeting Feedback Doc index tech files Supplier Renew Route Map
VST Ltd ISO9001:2015 8.5.6	**Control of changes** The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any	Doc index procedure tech files

	necessary actions arising from the review.	
VST Ltd ISO9001:2015 8.7.2	The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity.	Doc index QA system
Viamed Ltd ISO13485:2016 7.3.1	**General** The organization shall document procedures for design and development	/
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.	/
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	/
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.	
Viamed Ltd ISO13485:2016 7.3.4	**Design and development outputs** Design and development outputs shall: 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).	
Viamed Ltd ISO13485:2016 7.3.5	**Design and development review**	
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).	
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). 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).	
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	

VST

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Created:	17/May 1995	**Audit No 12**	
Revised:	15 May 2024		Page 7 of 9
Audit Date		Auditor	ISO

	realization processes. Records of changes, their review and any necessary actions shall be maintained (see 4.2.5).	✓

Paper files are becoming obsolete as electronic documentation supersedes them.
All CE Technical files should be in Intrastats Document Index.
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.	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.	VST Does not have own products Do have tech file	Y
3	Check Cross reference in Intrastats – Family Types. ISO – Tech Files Are all the Products present review	N/A	
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.	N/A	
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.	N/A	
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.	N/A	

VST

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Created:	17/May 1995	**Audit No 12**	
Revised:	15 May 2024		Page 8 of 9
Audit Date		Auditor	ISO

7	Are MDA guidelines are available for classification information. In ISO- Tech Files	This is an Intrastats automatic process when developing a new product.	N/A
8	Check that form RG2 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. *RG2 form discontinued. As of 2016 DORS MHRA account required.	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 No VST products of our own		
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

List Processes Per Title VST

ISO Controller					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Referenced in Document
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.	50 Managing Director 32 5078	14 Company Secretary Audit 22 327856	Freq 1 Risk 3 Overall 3	Task 2M Audit 12M	
PROCESSID **7172**	50		Freq 1	Task 2M	

Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.	Managing Director 325078 ✓		Risk 1 Overall 1		
Audits					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Referenced in Document
PROCESSID **7725** To carry out Audit 12 CE Files Viamed	324489 ✓ Viamed Audit	16 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7773** To carry out Audit 12 CE Files VST	324483 ✓ VST Audit	176 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	