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.	
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.	
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 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)	
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.	
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.	
VST Ltd	**Design and development planning**	

ISO9001:2015 8.3.2	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; 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.	
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.	
VST Ltd ISO9001:201	**Control of changes** The organization shall review and control changes for production or	

5 8.5.6	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 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.	
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 realization processes. Records of changes, their review and any necessary actions shall be maintained (see 4.2.5).	