Internal Audit Check list

VANDAGRAPH SENSOR TECHNOLOGY LTD

Design

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VST Ltd ISO9001:2015 8.1	**Operational planning and control** The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining, maintaining and retaining documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) to demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the organizations operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4).	Feedback Management Renew Route map Doc index Supplier Renew QA systems
VST Ltd ISO9001:2015 8.3.1 General	The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.	Doc index, tech files marketing QA system.
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; 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	Tech files Doc index marketing index Feedback. Supplier renew

	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.	management Renew. Feedback. marketing Doc index Tech files.
VST Ltd ISO9001:2015 8.3.4	**Design and development controls** The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained. NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted	QA systems Doc index Tech files Feedback. PMS

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	separately or in any combination, as is suitable for the products and services of the organization.	
VST Ltd ISO9001:2015 8.3.5	**Design and development outputs** The organization shall ensure that design and development outputs: a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. The organization shall retain documented information on design and development outputs.	Renew meeting marketing index Doc index
VST Ltd ISO9001:2015 8.3.6	**Design and development changes** The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts.	Tech files Doc index issues.
VST Ltd ISO9001:2015 8.5.1	**Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any	Doc index Procedures tech files QA system calibration index

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	required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	

	QUESTION:	**RESPONSE:**	**Y/ N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory. Nothing outstanding		Y
2	Technical File Reviewed ID: Task 54		Y
3	Check that the final design responsibility is a Sole Authority.	Top management VOP 17	Y
4	Check that all products are C.E. marked and Viamed products have a C.E. file. VST	Intrastats	Y
5	Pick 5 Products from the Files product list one file VST		
6	Declaration on Conformance Certificates present		Y
7	Verify that EMC testing has been identified where required.		NA
8	Are the latest BS ISO MDD requirements are available List DOC IDs		NA
9	Check that product classification is done to MDD principles.		NA
10	Verify that each design was initiated from a job description & specification		NA
11	Has each design has received a job number and a job progress form		NA
12	Verify the existence of a design documentation checklist.		NA
13	Check that estimated times have been noted. Electronic timing being introduced	No New Design	NA
14	Have final testing requirements, and test criteria, been identified		
15	Have concession notes have been raised on non-approved suppliers		
16	Check that current status is identified on a regular basis.		
17	Verify that design reviews are undertaken and that records are retained		

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18	Check that any amendments to design are logged No New Design		
19	Check that design output records are verified against design input No Design		NA
20	Does design verification comply with COP 16 - 7.7.1 - .4		NA
21	Check that clinical trials have been carried out and relevant records retained		NA
22	Verify that design validation has been carried out as required by form QC30	No Design	NA
23	Check that any design changes have been identified, recorded and approved	No Design	Y
24	Check that CE files are complete, correct and maintained		NA
25	Are design components kept separate from stock and adequately stored		NA
26	Are design component stocks labelled		NA
27	Check the existence of design compliance forms		NA
28	Check that these files are maintained		Y

List Processes Per Title

ADD THE CURRENT PROCESSES TO THIS SECTION .THESE ARE FOUND ON THE DOCUMENT PAGE

ISO Controller						
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes	
PROCESSID **5887** To Keep Products and Services up-to date with current regulations and standards	Task: 235 350509 ✓ Managing Director Audit :	Freq 2 Risk 2 Overall 4	Task 3M			
Product Controller						
Process Scope	**Roll Task**	**Risk**	**Action**	*	Notes	

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	Roll Audit						
PROCESSID **7045** Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body. First Check the Stockbox -> QA Fails Review (Slow Page) in case there are any products that have a New repair code that requires a risk assesment Carry out the Technical File PMS Form for Each OBL and Viamed Product Using procedure VM3COP27.11 See VM3COP18	Task: 50 348370 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 2M				
Audits							
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes		
PROCESSID **7716** To carry out Audit 03 Design Control Viamed	Task: Audit :22 350889 ✓ Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M				
PROCESSID **7764** To carry out Audit 03 Design Control VST	Task: Audit :193 350895 ✓ Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M				
Accounts Processes							
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes		
PROCESSID **7919** send a report to the managing director of what is happening with the debtors from the last month, include problems and payments due.	Task: 928 350944 ✓ Company Secretary Audit :929 348443 ✓ Office Processes	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M				

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Can add to issue and redirect						

Rolling Tasks Linked to Document :Task (22) Task (50) Task (235) Task (928) Task (193)