Internal Audit Check list

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Design

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Viamed Ltd ISO13485:2016 4.2.3 Medical device file	**Documentation requirements** For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity with the requirement of this International Standard and compliance with applicable regulatory requirements. The content of the file(s) shall include, but is not limited to: a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use; b) specifications for product; c) specifications or procedures for manufacturing, packaging, storage, handling and distribution; d) procedures for measuring and monitoring; e) as appropriate, requirements for installation; f) as appropriate, procedures for servicing.	Doc index Technical files Roles + titles Procedures
Viamed Ltd ISO13485:2016 7.1	**Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971.	Tech files management Renew. Route map Doc index
Viamed Ltd ISO13485:2016 7.3.1	**General** The organization shall document procedures for design and development	Doc index

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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 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 issues.
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.	Doc index Tech files QA files Route map Roles + titles Tech files Doc index
Viamed Ltd ISO13485:2016	**Design and development outputs** Design and development outputs shall:	

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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).	Renew meetings
Viamed Ltd ISO13485:2016 7.3.5	**Design and development review** At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to: a) evaluate the ability of the results of design and development to meet requirements; b) identify and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel. Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5).	Tech files Doc index Renew meeting QA System.
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).	QA system Tech files Issues Management Renew.
Viamed Ltd ISO13485:2016	**Design and development validation** Design and development validation shall be performed in	

7.3.7	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).	Procedures Roles + Hris Tech files Doc index
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	Tech files Doc index

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).

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7.5.6

Validation of processes for production and service provision
The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.
Validation shall demonstrate the ability of these processes to achieve planned results consistently.
The organization shall document procedures for validation of processes including:
a) defined criteria for review and approval of the processes;
b) equipment qualification and qualification of personnel;
c) use of specific methods, procedures and acceptance criteria;
d) as appropriate, statistical techniques with rationale for sample sizes
e) requirements for records (see 4.2.5);
f) revalidation, including criteria for revalidation;
g) approval of changes to the processes.
The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications.
Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

Doc index
Bar code system
Procedures
Management Renew.
Training Record
Calibration index

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	QUESTION:	RESPONSE:	Y/ N

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This Audit was to assess MDD. We do not design MDR

1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory. Nothing outstanding task 50.		Y
2	Technical File Reviewed ID:		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.	Intrastats	Y
5	Pick 5 Products from the Files product list No products.		N/A
6	Declaration on Conformance Certificates present MDD		Y
7	Verify that EMC testing has been identified where required. No products		Y
8	Are the latest BS ISO MDD requirements are available List DOC IDs MDD No MDR products		Y
9	Check that product classification is done to MDD principles. We do not No MDR	Design	Y
10	Verify that each design was initiated from a job description & specification		Y
11	Has each design has received a job number and a job progress form		Y
12	Verify the existence of a design documentation checklist.		Y
13	Check that estimated times have been noted. Electronic timing being introduced		Y
14	Have final testing requirements, and test criteria, been identified	No products	Y
15	Have concession notes have been raised on non-approved suppliers	No products	Y
16	Check that current status is identified on a regular basis.	No products	Y
17	Verify that design reviews are undertaken and that records are retained	No Products	Y
18	Check that any amendments to design are logged No amedments		N/A
19	Check that design output records are verified against design input	No products	Y
20	Does design verification comply with COP 16 - 7.7.1 - .4	No products	Y
21	Check that clinical trials have been carried out and relevant records retained	No products	Y
22	Verify that design validation has been carried out as required by form QC30	No products	Y
23	Check that any design changes have been identified, recorded and approved	No products.	Y

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24	Check that CE files are complete, correct and maintained Task SO yearly Renewed.	No Products	Y
25	Are design components kept separate from stock and adequately stored	No products	Y
26	Are design component stocks labelled Barcodes	No products.	Y
27	Check the existence of design compliance forms	No products.	Y
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

List Processes Per Title

Clone from Docid

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** **Roll Audit**	**Risk**	**Action**	*	Notes
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 ->	Task: 50 348370✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 2M		

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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					
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. Can add to issue and redirect	Task: 928 350964 Company Secretary Audit :929 348643 Office Processes	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M		

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