Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016

BOUNDRIES/EXCLUSIONS to SYSTEM

Version Date: 11 Aug 2020

Listing of Current Sections

Section	Reason for Exclusion	
6 Contamination control	**Viamed does not have any Sterile Products,**	
6.4.2 As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes. **Contamination control**	**Viamed does not have any Sterile Products,** **Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 01 Aug 2019	**Viamed does not have any Sterile Products,** **Process: 39** Enviromental Policy Document Review 16 Feb 2016 **Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016 **Process: 7714** Audit 01 Picking Packing Viamed 24 Aug 2016 **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016
7 Determination of requirements related to product	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices**	
7.2.1 The organization shall determine: a) requirements specified by the customer, including the requirements for delivery and postdelivery activities; b) requirements not stated by the customer but necessary for specified or intended use, as known; c) applicable regulatory requirements related to the product; d) any user training needed to ensure specified performance and safe use of the medical device; e) any additional requirements determined by the organization **Determination of requirements related to product**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 03 Contract Review, Enquires, Office Processes** Revision Document ID33748 Date Revision 18 Mar 2020 Reviewed 18 Mar 2020 **Audit 22 Post Market Survellance** Revision Document ID41428 **Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 **Audit 02 Contract Review and Sales Order Processing** Revision Document ID33205 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **VM3COP20.31 Export Order Processing** Revision Document ID22016 Date Revision 15 Sep 2017 Reviewed 15 Sep 2017	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7732** Audit 22 Post Market Survellance Viamed 24 Aug 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017 **Process: 5** Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017 **Process: 7** Responsibility Allocation : Checking Of Sales Orders 16 Feb 2016 **Process: 7734** Responsibility Allocation : Humanmed Order Processing 25 Aug 2016 **Process: 5** Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016 **Process: 7734** Responsibility Allocation : Humanmed Order Processing 25 Aug 2016 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017

VM3COP03.01 Order Processing Priorities
Revision Document ID20049
Date Revision 15 May 2017
Reviewed 15 May 2017
VM3COP20.30 UK Order Processing
Revision Document ID24341
Date Revision 29 Nov 2017
Reviewed 29 Nov 2017
VM3COP03.07 Humanmed Order Checking
Revision Document ID22266
Date Revision 27 Sep 2017
Reviewed 27 Sep 2017
VM3COP03.08 Humanmed Order Processing
Revision Document ID24775
Date Revision 22 Dec 2017
Reviewed 22 Dec 2017
VM3COP20.32 Order Checking
Revision Document ID34889
Date Revision 01 Apr 2020
Reviewed 01 Apr 2020
Infant Resuscitation Cabinet - Training Assessment Form
Revision Document ID14334
Date Revision 25 Sep 2014
Reviewed 25 Sep 2014
Oxygen Sensor Training Powerpoint
Revision Document ID15736
Date Revision 24 Sep 2015
Reviewed 25 Oct 2016
Oxygen Sensor Training Video
Revision Document ID15737
Date Revision 24 Sep 2015
Reviewed 24 Sep 2015
Resuscitation Unit and TC400 Training Information Resuscitation Cabinet Training
Revision Document ID4111
Date Revision 09 Jul 2008
Reviewed 09 Jul 2008
Resuscitation Unit Maintenance Therapy Equipment Suction Controller Unit and TC400 Training Information Therapy Workshop Inst.
Revision Document ID4122
Date Revision 09 Jul 2008
Reviewed 09 Jul 2008
Single Use Surgical Training Information certificates
Revision Document ID20220
Date Revision 19 May 2017
Reviewed 19 May 2017
SpO2 800 series Training Information
Revision Document ID12687
Date Revision 02 Jul 2013
Reviewed 02 Jul 2013
TECcare Training Material
Revision Document ID11826
Date Revision 11 Jun 2012
Reviewed 11 Jun 2012
Temperature Probe Training Material
Revision Document ID18169
Date Revision 05 Dec 2016
Reviewed 05 Dec 2016
Tom Thumb Training Information
Revision Document ID7880
Date Revision 07 Mar 2011
Reviewed 07 Mar 2011

	Tom Thumb Training Information 2009 Revision Document ID15644 Date Revision 16 Sep 2015 Reviewed 16 Sep 2015 **Tom Thumb Training Information Training Manual Training Information** Revision Document ID2973 Date Revision 31 Jan 2008 Reviewed 31 Jan 2008 **Tom Thumb Training Information Training V1.1** Revision Document ID15641 Date Revision 16 Sep 2015 Reviewed 16 Sep 2015 **Training information Infant Resusitation Unit** Revision Document ID8665 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **VM-2500 Product Training Materials - Frequently Asked Questions** Revision Document ID6967 Date Revision 17 Mar 2010 Reviewed 17 Mar 2010 **VM-2500 Product Training Materials Capnography Product Application Notes** Revision Document ID6749 Date Revision 08 Feb 2010 Reviewed 08 Feb 2010 **VM-2500 Product Training Materials Capnography Product Presentation MASTER** Revision Document ID6750 Date Revision 08 Feb 2010 Reviewed 08 Feb 2010 **VM-2500 Product Training Materials Mainstream or Sidestream Capnography** Revision Document ID6753 Date Revision 08 Feb 2010 Reviewed 08 Feb 2010 **VM3COP12.01 Viamed Policy on End User Training UK** Revision Document ID23571 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 **Audit 01 Picking packing** Revision Document ID33201 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 16 Sales and Marketing** Revision Document ID41236 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	
7.3 **Design and development**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices**
7.3.1 The organization shall document procedures for design and development **General**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 24 Aug 2016

	Audit 03 Design Control Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 20 Process verification to Managment** Revision Document ID41410 **Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 **BSI Technical File Design File Requirements Dosier** Revision Document ID4959 Date Revision 29 Dec 2008 Reviewed 29 Dec 2008 **CE & Design files re-organisation** Revision Document ID9085 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Chart 04 Design and Development** Revision Document ID8678 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 17 Design Repairs** Revision Document ID8690 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 30 System Design Plan** Revision Document ID8703 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **New Project Design File Content** Revision Document ID9093 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **VM3COP16 Design and Design Changes Design requirements** Revision Document ID7396 Date Revision 10 Jan 2011 Reviewed 10 Jan 2011 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	
7.3.2 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 **Design and development planning**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document ID17824 Date Revision 03 Nov 2016 Reviewed 25 Nov 2019 **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks** Revision Document ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **VM3COP16 Design and Design Changes Design requirements** Revision Document ID7396 Date Revision 10 Jan 2011	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 24 Aug 2016 **Process: 7720** Audit 08 Training Viamed 24 Aug 2016

	Reviewed 10 Jan 2011 **VM3COP27.07 Project Manager** Revision Document ID12734 Date Revision 11 Jul 2013 Reviewed 11 Jul 2013 **VM3COP27.12 Clinical Evaluation Risk assessment Technical Files** Revision Document ID15453 Date Revision 11 Aug 2015 Reviewed 11 Aug 2015 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 20 Process verification to Managment** Revision Document ID41410 **Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 **Audit 08 Training, Competence and Human Resources** Revision Document ID40199 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020 **QC 28B Design Changes** Revision Document ID25508 Date Revision 05 Mar 2018 Reviewed 05 Mar 2018 **Generic CE File Attached to All Assignment of responsibility Risk Management** Revision Document ID7742 Date Revision 02 Mar 2011 Reviewed 02 Mar 2011	
7.3.3 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. **Design and development inputs**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 20 Process verification to Managment** Revision Document ID41410 **Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020 **Audit 23 Analysis of Data** Revision Document ID41446 **Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 24 Aug 2016
7.3.4 Design and development outputs shall: a) meet the input requirements for design and development; b) provide appropriate information for purchasing, production and service provision;	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016

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). **Design and development outputs**	**Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 23 Analysis of Data** Revision Document ID41446 **Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	
7.3.5 **Design and development review**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices**
7.3.5 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).	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016
7.3.6 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). **Design and development verification**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Top Level Document: VOP 15 Data and Information Analysis** Revision Document ID31056 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices**
7.3.7	**Excluded while MDR**	**Excluded while MDR settles in, And Viamed has No**

Design and development validation	**settles in, And Viamed has No production of any Medical Devices** **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020 **QC 30b Project Verification & Validation Summary Master** Revision Document ID25482 Date Revision 01 Mar 2018 Reviewed 01 Mar 2018	**production of any Medical Devices**
7.3.7 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).	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Top Level Document: VOP 15 Data and Information Analysis** Revision Document ID31056 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 24 Aug 2016
7.3.8 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). **Design and development transfer**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 12 CE Files**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016

	Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	
7.3.9 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). **Control of design and development changes**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 17 Design Research and Development** Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020 **QC 28B Design Changes** Revision Document ID25508 Date Revision 05 Mar 2018 Reviewed 05 Mar 2018	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016
7.3.10 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. **Design and development files**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 12 CE Files** Revision Document ID41224 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016
7.5.1 Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved. **Control of production and service provision**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 22 Picking and Packing Dispatch and Goods Out** Revision Document ID31048 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document ID31076 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **Top Level Document: VOP 06 Measurement Control Viamed VST, Calibration, QA Stock** Revision Document ID31080 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **Top Level Document: VOP 08 Production, Reworks, New Production** Revision Document ID31072 Date Revision 30 Sep 2019	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7714** Audit 01 Picking Packing Viamed 24 Aug 2016 **Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016 **Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016 **Process: 7727** Audit 15 Production Viamed 24 Aug 2016

	Reviewed 30 Sep 2019 **VM3COP20.37 Generating a New Service Visit** Revision Document ID17116 Date Revision 28 Jun 2016 Reviewed 28 Jun 2016 **Audit 06 Calibration** Revision Document ID40191 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020 **Audit 01 Picking packing** Revision Document ID33201 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 07 Handling and Storage** Revision Document ID40195 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020 **Audit 15 Production** Revision Document ID41232 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020 **Audit 24 Service Logs** Revision Document ID41450 **Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 **Audit 09 Goods Inward and Product Identity** Revision Document ID40203 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020	
7.5.2 The organization shall document requirements for cleanliness of product or contamination control of product if: a) product is cleaned by the organization prior to sterilization or its use; b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use; c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; e) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process. **Cleanliness of product**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document:** **VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 01 Aug 2019 **Audit 07 Handling and Storage** Revision Document ID40195 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 **Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016
7.5.3 The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5). **Installation activities**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Resuscitation Unit and TC400 Maintenance TC400 Installation Instructions** Revision Document ID8155 Date Revision 24 Mar 2011 Reviewed 24 Mar 2011 **Resuscitation Unit Instructions for Use / Installation Ceratherm v3.01 Resuscitation Unit and TC400 Maintenance** Revision Document ID8178 Date Revision 24 Mar 2011 Reviewed 24 Mar 2011 **Resuscitation Unit Instructions for Use / User Manual Nufer**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016

	Wall Mount Installation Revision Document ID1312 Date Revision 19 Mar 2007 Reviewed 19 Mar 2007 **VM3COP51.20 Resuscitation Cabinet Installation Instructions** Revision Document ID18221 Date Revision 12 Dec 2016 Reviewed 12 Dec 2016 **Audit 24 Service Logs** Revision Document ID41450 **Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	
7.5.4 If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5). **Servicing activities**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VM3COP50.13 Quality Control Tom Thumb** Revision Document ID31154 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **Top Level Document: VOP 09 Repairs and Servicing** Revision Document ID31020 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **VM3COP20.27 Annual Services for Resuscitation Cabinets** Revision Document ID24509 Date Revision 06 Dec 2017 Reviewed 06 Dec 2017 **VM3COP20.37 Generating a New Service Visit** Revision Document ID17116 Date Revision 28 Jun 2016 Reviewed 28 Jun 2016 **VM3COP50.12 Quality Control / Service Checks Tom Thumb** Revision Document ID15367 Date Revision 05 Aug 2015 Reviewed 05 Aug 2015 **Audit 24 Service Logs** Revision Document ID41450 **Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 **Audit 11 Repairs, Servicing and Returns** Revision Document ID41150 **Date Revision 02 Aug 2020 Reviewed 02 Aug 2020 **Audit 23 Analysis of Data** Revision Document ID41446 **Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 **Audit 14 Complaints and Corrective Actions** Revision Document ID41228 **Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Process: 5857** Customer Service Logs 17 Feb 2016 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016
7.5.5 The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices. **Particular requirements for sterile medical devices**	**Viamed does not have any Sterile Products,** **Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 01 Aug 2019	**Viamed does not have any Sterile Products,** **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016

7.5.6 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). **Validation of processes for production and service provision**	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices** **Top Level Document: VOP 27 Software Validation** Revision Document ID31064 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **Top Level Document: VOP 15 Data and Information Analysis** Revision Document ID31056 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 **VM3COP18 Post Market Surveilance** Revision Document ID8106 Date Revision 21 Mar 2011 Reviewed 21 Mar 2011 **Audit 03 Design Control** Revision Document ID33209 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 **Audit 24 Service Logs** Revision Document ID41450 **Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 **Audit 11 Repairs, Servicing and Returns** Revision Document ID41150 **Date Revision 02 Aug 2020 Reviewed 02 Aug 2020 **Audit 10 Documentation Control** Revision Document ID41141 **Date Revision 02 Aug 2020 Reviewed 02 Aug 2020	**Excluded while MDR settles in, And Viamed has No production of any Medical Devices**
7.5.7 The organization shall document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems. Processes for sterilization and sterile barrier systems shall be validated prior to implementation and following product or process changes, as appropriate. 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). NOTE Further information can be found in ISO 11607-1 and ISO 11607-2. **Particular requirements for validation of processes for sterilization and sterile barrier systems**	**Viamed does not have any Sterile Products,** **Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 01 Aug 2019	**Viamed does not have any Sterile Products,**
7.5.9.2 The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety	**Viamed does not have any implantable medical devices,** **Top Level Document: VM3COP02.01 Exclusions to**	**Viamed does not have any implantable medical devices,**

and performance requirements. The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5). **Particular requirements for implantable medical devices**	**Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 01 Aug 2019	