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

Version: 1508585850

Listing of Current Sections

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4 Quality management system		
4.1 **Quality management system**	**ISO 13485:2016 Viamed Summary Listing** Revision Document ID23089 Date Revision 21 Oct 2017 Reviewed 21 Oct 2017 **BS EN ISO 13485-2016** Revision Document ID19400 Date Revision 27 Mar 2017 Reviewed 27 Mar 2017	
4.1.1 The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document ID13377 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **BS5750 Viamed** Revision Document ID21353 Date Revision 10 Aug 2017 Reviewed 10 Aug 2017 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Viamed ISO 13485:2016**	**Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017

representative, importer or distributor.	**Scope** Revision Document ID22645 Date Revision 15 Oct 2017 Reviewed 15 Oct 2017	
4.1.2 The organization shall: a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization; b) apply a risk based approach to the control of the appropriate processes needed for the quality management system; c) determine the sequence and interaction of these processes.	**Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document ID21556 Date Revision 22 Aug 2017 Reviewed 11 Oct 2017 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **Chart 00 System Model** Revision Document ID8674 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 01 System and Documentation** Revision Document ID8675 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 02 Resource Management** Revision Document ID8676 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 03 Customer Requirements** Revision Document ID8677 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 04 Design and Development** Revision Document ID8678 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 05 Product Realisation** Revision Document ID8679 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 06 General Process Control** Revision Document ID8680 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 07 Measurement and Analysis** Revision Document ID8681	**Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016

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Chart 08 Correction and Prevention
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Chart 09 Management System
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Chart 10 Documentation
Revision Document ID8684
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Chart 15 Purchasing
Revision Document ID8688
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Chart 16 Internal Audits
Revision Document ID8689
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Chart 17 Design Repairs
Revision Document ID8690
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Chart 22 Stock Control
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Chart 23 Picking and Packing
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Chart 29 Sales Acquisition
Revision Document ID8702
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Chart 30 System Design Plan
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Reviewed 12 Oct 2011
Chart 31 Chart Interfaces
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Date Revision 12 Oct 2011
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Chart 32 Generic Sales Process
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Chart 33 Launch of a new product
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Reviewed 12 Oct 2011
Chart 34 Process Teams Org Chart

	Revision Document ID8707 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016	
4.1.3 For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).	**Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **VM3COP27.01 Searching Intrastats Issues** Revision Document ID6657 Date Revision 02 Nov 2009 Reviewed 02 Nov 2009 **VM3COP27.17 Complete Auto_calender Issues** Revision Document ID16995 Date Revision 26 May 2016 Reviewed 26 May 2016 **Issues Overview** Revision Document ID22272 Date Revision 27 Sep 2017 Reviewed 27 Sep 2017 **Intrastats overview** Revision Document ID8925 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Employee Roles** Revision Document ID20125 Date Revision 16 May 2017 Reviewed 16 May 2017 **Employee roles Example Process** Revision Document ID20129 Date Revision 16 May 2017 Reviewed 16 May 2017 **VM3COP27.02 Collecting Emails and Distributing** Revision Document ID20131 Date Revision 16 May 2017 Reviewed 16 May 2017 **Employee Roles Individual Processes** Revision Document ID20127 Date Revision 16 May 2017 Reviewed 16 May	**Process: 27** Management Reviews And Quality Audits 16 Feb 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 5889** Responsibility Allocation : Audit And Task - Audit 24 Feb 2016 **Process: 7714** Audit 01 Picking Packing Viamed 24 Aug 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016 **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 **Process: 7718** Audit 06 Calibration Viamed 24 Aug 2016 **Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016 **Process: 7720** Audit 08 Training Viamed 24 Aug 2016 **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7724** Audit 11 Repairs And Service Viamed 24 Aug 2016 **Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016 **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 **Process: 7727** Audit 15 Production Viamed 24 Aug 2016 **Process: 7728** Audit 17 Internal Audits Viamed 24 Aug 2016

	2017 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017	**Process: 7729** Audit 19 Health And Saftey Viamed 24 Aug 2016 **Process: 7731** Audit 21 Audit Of Audit Viamed 24 Aug 2016 **Process: 7732** Audit 22 Post Market Survellance Viamed 24 Aug 2016 **Process: 7733** Audit 23 Analysis Of Data Viamed 24 Aug 2016 **Process: 26** Company Resources 16 Feb 2016
4.1.4 For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.	**Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document ID13387 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016	**Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016
4.1.5 For each quality management system process, the organization shall: When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The	**Audit 05 Purchasing suppliers** Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016	**Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016

organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.		
4.1.6 For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. 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. Records of such activities shall be maintained (see 4.2.5).	**Top Level Document: VOP 27 Software Validation** Revision Document ID22427 Date Revision 04 Oct 2017 Reviewed 04 Oct 2017 **Intrastats Amendment Log** Revision Document ID20136 Date Revision 16 May 2017 Reviewed 16 May 2017 **Validation of Intrastats** Revision Document ID20140 Date Revision 16 May 2017 Reviewed 16 May 2017 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016	**Process: 7850** Software Validation Scan In Correct Product 01 Oct 2017 **Process: 7851** Software Validation Scan Un-QA Product To Order 01 Oct 2017 **Process: 7852** Software Validation Expired Stock 01 Oct 2017 **Process: 7853** Software Validation Non Sell Able Shelf 01 Oct 2017 **Process: 7854** Software Validation In Production List 01 Oct 2017 **Process: 7855** Software Validation - Production Lists 01 Oct 2017 **Process: 7856** Software Validation Unchecked Orders 01 Oct 2017 **Process: 7857** Software Validation Stock Tracking Check 01 Oct 2017 **Process: 7858** Software Validation Attempt To QA Some Stock 01 Oct 2017 **Process: 7861** Software Validation Of Training Documents Forced Reading 03 Oct 2017 **Process: 7865** Software Validation Conflicting Audits 07 Oct 2017 **Process: 7870** Software Validation Non Conformance Product Risk Feedback Loop 15 Oct 2017
4.2 **Documentation requirements**	**Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	

4.2.1 General The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	**Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document ID22684 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017 **Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document ID13377 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Explaination Quality Objectives** Revision Document ID18483 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document ID22062 Date Revision 16 Sep 2017 Reviewed 16 Sep 2017 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **VM3COP00.01 Company objectives** Revision Document	**Process: 23** Company Objectives 16 Feb 2016 **Process: 22** Company Policys 16 Feb 2016 **Process: 23** Company Objectives 16 Feb 2016 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7834** Financial Review 20 Sep 2017 **Process: 7862** Review The Audit Calender Screen 04 Oct 2017 **Process: 27** Management Reviews And Quality Audits 16 Feb 2016 **Process: 5877** Responsibility Allocation : Review Company Data 17 Feb 2016 **Process: 6843** Future Reviews - Waste 09 Mar 2016 **Process: 6861** Management Meeting Review Weekly Meeting 09 Mar 2016 **Process: 7037** Responsibility Allocation : Responsibility, authority and communication 09 Mar 2016 **Process: 7057** Responsibility Allocation : Complaints and Vigilance Notifications 09 Mar 2016 **Process: 7070** Management Review 09 Mar 2016 **Process: 7713** Review Roles And Responsibilitys 17 Aug 2016 **Process: 7830** Review Q.A. Failures Report 18 Sep 2017 **Process: 7837** Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 **Process: 7839** Review VIAMED Feedback - Customer Complaints 23 Sep 2017 **Process: 7842** Review VIAMED Product Feedback Negative 23 Sep 2017 **Process: 7845** 7.1.4 Environment Of Operations 25 Sep 2017 **Process: 7848** Review ISO Scopes 27 Sep 2017 **Process: 7849**

	ID22842 Date Revision 17 Oct 2017 Reviewed 17 Oct 2017	Review Product Failures New Codes 28 Sep 2017 **Process: 7120** General Maintenance Requirements 09 Mar 2016 **Process: 28** Supplier Review 16 Feb 2016 **Process: 5887** Review ISO/EN Documents 24 Feb 2016 **Process: 5889** Responsibility Allocation : Audit And Task - Audit 24 Feb 2016 **Process: 6828** Non Conformance Issues 09 Mar 2016 **Process: 6866** Internal Process Verification Complete Systems Review 09 Mar 2016 **Process: 7199** Non Conformities Review 09 Mar 2016 **Process: 7828** Review The Quality Policy Viamed 16 Sep 2017 **Process: 6821** Responsibility Allocation : VIAMED Management Meeting Supplier Review 09 Mar 2016 **Process: 7697** Yearly Pricing Review 09 May 2016 **Process: 57** Temporary Stock Notices 17 Feb 2016
4.2.2 Quality manual The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017 **Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document ID21556 Date Revision 22 Aug 2017 Reviewed 11 Oct 2017 **Structure of the documentation used in the quality management system** Revision Document ID18487 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 **Audit 10b Process Verification**	**Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016

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4.2.3 Medical device file 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.	**Top Level Document: VOP 17 Design Research and Development** Revision Document ID9182 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Route to Medical device files** Revision Document ID18495 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016	**Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017
4.2.4 Control of documents	**Top Level Document: VOP**	**Process: 7722**

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5. A documented procedure shall define the controls needed to: a) review and approve documents for adequacy prior to issue; b) review, update as necessary and re-approve documents; c) ensure that the current revision status of and changes to documents are identified; d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled; g) prevent deterioration or loss of documents; h) prevent the unintended use of obsolete documents and apply suitable identification to them. The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to	**01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document ID13377 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Explanation Control of documents** Revision Document ID21322 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 **VM3COP01 Document Updates / Amendment control** Revision Document ID22201 Date Revision 23 Sep 2017 Reviewed 23 Sep 2017 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **VM3COP14 Documentation** Revision Document ID9276 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	Audit 10 Documentation Control Viamed 24 Aug 2016

which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable		
4.2.5 Control of records Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable. The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document ID13377 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document ID6275 Date Revision 06 Aug 2009 Reviewed 06 Aug 2009 **VM3COP01 Document Updates / Amendment control** Revision Document ID22201 Date Revision 23 Sep 2017 Reviewed 23 Sep 2017 **VM3COP14.01 Disposition of Documents / Records.** Revision Document ID15464 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015 **Guide to Intrastats** Revision Document ID8924 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Intrastats overview** Revision Document ID8925 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **VM3COP14 Documentation** Revision Document ID9276 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug	**Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016

	2016 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	

5 Management commitment

5.1 Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by: a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; d) conducting management reviews; e) ensuring the availability of resources. **Management commitment**	**Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks** Revision Document ID13379 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure** Revision Document ID8672 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document ID22684 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017 **VM3COP02 Organisation Responsibilities Viamed** Revision Document ID17423 Date Revision 07 Sep 2016 Reviewed 07 Sep 2016 **Chart 01 System and Documentation** Revision Document ID8675 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 02 Resource Management** Revision Document ID8676 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **VM3COP19 Health and Safety** Revision Document	**Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016 **Process: 7833** Importance Of Effective Quality Management 20 Sep 2017 **Process: 27** Management Reviews And Quality Audits 16 Feb 2016 **Process: 7070** Management Review 09 Mar 2016 **Process: 7848** Review ISO Scopes 27 Sep 2017 **Process: 23** Company Objectives 16 Feb 2016

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5.2 Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.	**Top Level Document: VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** Revision Document ID22950 Date Revision 18	**Process: 7** Checking Of Sales Orders 16 Feb 2016 **Process: 11** Distribution Of Mail 16 Feb 2016 **Process: 5882** Responsibility Allocation : Send Post To

Customer focus	Oct 2017 Reviewed 18 Oct 2017 **Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document ID17419 Date Revision 06 Sep 2016 Reviewed 06 Sep 2016 **Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document ID13387 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **VM3COP20.01 Post In Distributing the Post** Revision Document ID18641 Date Revision 10 Feb 2017 Reviewed 10 Feb 2017 **Audit 02 Contract Review and Sales Order Processing** Revision Document ID17280 Date Revision 16 Aug 2016 Reviewed 16 Aug 2016 **MISC Incident Report** Revision Document ID240 Date Revision 17 Aug 2006 Reviewed 17 Aug 2006 **How to Hold Intrastat Meetings** Revision Document ID8928 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 04 Accounts and Finance** Revision Document ID22086 Date Revision 17 Sep 2017 Reviewed 17 Sep 2017 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 16 Sales and Marketing** Revision Document ID22080 Date Revision 17	Humanmed 24 Feb 2016 **Process: 2** Answering Telephones 16 Feb 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016

	Sep 2017 Reviewed 17 Sep 2017	
5.3 Top management shall ensure that the quality policy: a) is applicable to the purpose of the organization; b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; c) provides a framework for establishing and reviewing quality objectives; d) is communicated and understood within the organization; e) is reviewed for continuing suitability. **Quality policy**	**Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document ID22684 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document ID22062 Date Revision 16 Sep 2017 Reviewed 16 Sep 2017 **VM3COP00.01 Company objectives** Revision Document ID22842 Date Revision 17 Oct 2017 Reviewed 17 Oct 2017 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016	**Process: 23** Company Objectives 16 Feb 2016 **Process: 22** Company Policys 16 Feb 2016 **Process: 23** Company Objectives 16 Feb 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7833** Importance Of Effective Quality Management 20 Sep 2017 **Process: 7828** Review The Quality Policy Viamed 16 Sep 2017 **Process: 7827** Review The Quality Policy VST 16 Sep 2017
5.4 **Planning**		
5.4.1 Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. **Quality objectives**	**Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document ID13387 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **VM3COP18 Post Market Surveilance** Revision Document ID8106 Date Revision 21 Mar 2011 Reviewed 21 Mar 2011 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep	**Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 7830** Review Q.A. Failures Report 18 Sep 2017 **Process: 26** Company Resources 16 Feb 2016 **Process: 5877** Responsibility Allocation : Review Company Data 17 Feb 2016

	2017 **Explaination Quality Objectives** Revision Document ID18483 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Viamed Top Level Quality Objectives** Revision Document ID22429 Date Revision 04 Oct 2017 Reviewed 04 Oct 2017	
5.4.2 Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. **Quality management system planning**	**Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document ID21556 Date Revision 22 Aug 2017 Reviewed 11 Oct 2017 **Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document ID22684 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **Explaination Quality Objectives** Revision Document ID18483 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 **Explanation Control of documents** Revision Document ID21322 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 **Route to Medical device files** Revision Document	**Process: 11** Distribution Of Mail 16 Feb 2016 **Process: 5882** Responsibility Allocation : Send Post To Humanmed 24 Feb 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016

	ID18495 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 **VM3COP20.01 Post In Distributing the Post** Revision Document ID18641 Date Revision 10 Feb 2017 Reviewed 10 Feb 2017 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document ID22062 Date Revision 16 Sep 2017 Reviewed 16 Sep 2017 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Viamed Top Level Quality Objectives** Revision Document ID22429 Date Revision 04 Oct 2017 Reviewed 04 Oct 2017 **VM3COP00.01 Company objectives** Revision Document ID22842 Date Revision 17 Oct 2017 Reviewed 17 Oct 2017	
5.5 **Responsibility, authority and communication**		
5.5.1 Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to	**Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks** Revision Document ID13379 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure**	**Process: 7720** Audit 08 Training Viamed 24 Aug 2016 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 7713** Review Roles And Responsibilitys 17 Aug 2016 **Process: 6837** Personnel Requirements and Training 09 Mar 2016

perform these tasks. **Responsibility and authority**	Revision Document ID21556 Date Revision 22 Aug 2017 Reviewed 11 Oct 2017 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **VM3COP02 Organisation Responsibilities Viamed** Revision Document ID17423 Date Revision 07 Sep 2016 Reviewed 07 Sep 2016 **Chart 01 System and Documentation** Revision Document ID8675 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Chart 02 Resource Management** Revision Document ID8676 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Viamed Company Format Company format 1** Revision Document ID9039 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Viamed Company Format Company format 2** Revision Document ID9040 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Viamed Company Format Company format 3** Revision Document ID9041 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Viamed Company Format Company format 4** Revision Document ID9042 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 08 Training, Competence and Human Resources** Revision Document ID9033 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017		

	Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Revision Document ID21806 Date Revision 05 Sep 2017 Reviewed 05 Sep 2017	
5.5.2 Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes: a) ensuring that processes needed for the quality management system are documented; b) reporting to top management on the effectiveness of the quality management system and any need for improvement; c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization. **Management representative**	**Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017	**Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 7833** Importance Of Effective Quality Management 20 Sep 2017
5.5.3 Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. **Internal communication**	**VM3COP27.01 Searching Intrastats Issues** Revision Document ID6657 Date Revision 02 Nov 2009 Reviewed 02 Nov 2009 **Intrastats overview** Revision Document ID8925 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	
5.6 Management review		
5.6.1 The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability,	**How to Hold Intrastat Meetings** Revision Document ID8928 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun	**Process: 7846** ISO System Management Review 26 Sep 2017 **Process: 27** Management Reviews And Quality Audits 16 Feb 2016 **Process: 7070** Management Review 09 Mar 2016

adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained **General**	2017 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Management Review** Revision Document ID19792 Date Revision 05 May 2017 Reviewed 05 May 2017 **Management reviews** Revision Document ID19801 Date Revision 05 May 2017 Reviewed 05 May 2017	
5.6.2 Review input The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document ID17419 Date Revision 06 Sep 2016 Reviewed 06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document ID13697 Date Revision 12 May 2014 Reviewed 12 May 2014 **Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document ID21556 Date Revision 22 Aug 2017 Reviewed 11 Oct 2017 **Top Level Document: VOP10.01 VM3COP10.01 Preventative Actions** Revision Document ID22462 Date Revision 05 Oct 2017 Reviewed 05 Oct 2017 **Chart 27 Customer Complaints Chart 27** Revision Document ID8700 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011	**Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 **Process: 7839** Review VIAMED Feedback - Customer Complaints 23 Sep 2017 **Process: 7842** Review VIAMED Product Feedback Negative 23 Sep 2017 **Process: 7846** ISO System Management Review 26 Sep 2017 **Process: 7848** Review ISO Scopes 27 Sep 2017 **Process: 7849** Review Product Failures New Codes 28 Sep 2017 **Process: 7871** Review Exclusion From Viamed 13485:2016 And VST 9001:2015 15 Oct 2017 **Process: 7837** Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 **Process: 7830** Review Q.A. Failures Report 18 Sep 2017 **Process: 7741** Review Ethical Policy 14 Sep 2016 **Process: 7713** Review Roles And Responsibilitys 17 Aug 2016 **Process: 7070** Management Review 09 Mar 2016 **Process: 6931** Customer Complaints 09 Mar 2016

	VM3COP18 Post Market Surveilance Revision Document ID8106 Date Revision 21 Mar 2011 Reviewed 21 Mar 2011 **How to Hold Intrastat Meetings** Revision Document ID8928 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 21 Audit of Audit** Revision Document ID9037 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	**Process: 7091** Calibration Index 09 Mar 2016
5.6.3 The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to: a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; b) improvement of product related to customer requirements; c) changes needed to respond to applicable new or revised regulatory requirements;	**Issues Overview** Revision Document ID22272 Date Revision 27 Sep 2017 Reviewed 27 Sep 2017 **VM3COP27.01 Searching Intrastats Issues** Revision Document ID6657 Date Revision 02 Nov 2009 Reviewed 02 Nov 2009 **Management Review** Revision Document ID19792 Date Revision 05 May 2017 Reviewed 05 May 2017 **Management reviews** Revision Document ID19801 Date Revision 05 May 2017 Reviewed 05 May 2017 **Management reviews minutes**	**Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016

d) resource needs. **Review output**	Revision Document ID19803 Date Revision 05 May 2017 Reviewed 05 May 2017 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	

6 Resource management

6 Resource management **Resource management**		
6.1 The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness; b) meet applicable regulatory and customer requirements. **Provision of resources**	**Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017	**Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016
6.2 **Human resources**	**Audit 08 Training, Competence and Human Resources** Revision Document ID9033 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	
6.2 Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel	**VM3COP12 Training** Revision Document ID8714 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **Audit 08 Training, Competence and Human Resources** Revision Document ID9033 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	**Process: 7720** Audit 08 Training Viamed 24 Aug 2016

performing work affecting product quality; b) provide training or take other actions to achieve or maintain the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) maintain appropriate records of education, training, skills and experience (see 4.2.5). NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.	**Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document ID21806 Date Revision 05 Sep 2017 Reviewed 05 Sep 2017	
6.3 The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work	**Top Level Document: VOP 06 Measurement Control Viamed, Calibration, QA Stock** Revision Document ID6268 Date Revision 06 Aug 2009 Reviewed 06 Aug 2009 **VM3COP11 Calibration** Revision Document ID8713 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **HSE Fire Exit / Escape Route Ground Floor plans** Revision Document ID18653 Date Revision 14 Feb 2017 Reviewed 14 Feb 2017 **HSE Fire Exit / Escape Route Ground Floor plans Document** Revision Document ID2558 Date Revision 01 Aug 2007 Reviewed 01 Aug 2007 **HSE Fire Risk Assessment** Revision Document ID21790 Date Revision 04 Sep 2017 Reviewed 04 Sep 2017 **HSE Fire Safety Risk Assessment** Revision Document ID892 Date Revision 25 Oct 2006	**Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016 **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 **Process: 6855** Risk Assessment HSE 09 Mar 2016 **Process: 6856** Fire Alarms 09 Mar 2016 **Process: 7092** P.A.T. Testing 09 Mar 2016 **Process: 54** Responsibility Allocation : Gents Toilets 17 Feb 2016 **Process: 5907** Hoover Warehouse 03 Mar 2016 **Process: 5908** Sweep Warehouse 03 Mar 2016 **Process: 5909** Empty Warehouse Bins 03 Mar 2016 **Process: 5911** Responsibility Allocation : Clear Cardboard 03 Mar 2016 **Process: 5856** Cleaning The Kitchen 17 Feb 2016 **Process: 7802** Clean Kitchen Sides 22 May 2017 **Process: 7803** Dishwashing 22 May 2017 **Process: 7804** Sweep Kitchen Floor 22 May 2017

environment and monitoring and measurement. Records of such maintenance shall be maintained **Infrastructure**	Reviewed 25 Oct 2006 **HSE Fire / Exit Escape route Basement floor plans** Revision Document ID15401 Date Revision 07 Aug 2015 Reviewed 26 Sep 2016 **HSE Fire / Exit Escape route Ghyll House floor plans** Revision Document ID15403 Date Revision 07 Aug 2015 Reviewed 26 Sep 2016 **Ghyll House Fire Certificate** Revision Document ID12303 Date Revision 15 Mar 2013 Reviewed 15 Mar 2013 **CPM 21 Fire Exit / Escape Route Procedures** Revision Document ID21892 Date Revision 07 Sep 2017 Reviewed 07 Sep 2017 **FIRE Report Premisis** Revision Document ID17505 Date Revision 26 Sep 2016 Reviewed 26 Sep 2016 **VM3COP20.35 Ups Calculator** Revision Document ID17149 Date Revision 05 Jul 2016 Reviewed 05 Jul 2016 **VM3COP20.07 UPS Procedures** Revision Document ID8722 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **VM3COP03.05 Procedures for customer returning goods on our UPS account number** Revision Document ID17155 Date Revision 05 Jul 2016 Reviewed 05 Jul 2016 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **Audit 07 Handling and Storage**	**Process: 7805** Empty Kitchen Bins 22 May 2017 **Process: 7806** Watering Plants 22 May 2017 **Process: 56** Warehouse Outside Heating Guard 17 Feb 2016 **Process: 5919** Check Out Side Drain 05 Mar 2016 **Process: 5921** Clearing Water Downstairs 05 Mar 2016 **Process: 7120** General Maintenance Requirements 09 Mar 2016 **Process: 7742** Boiler Check 26 Sep 2016 **Process: 7756** Carbon Monoxide Alarm 05 Jan 2017 **Process: 7820** North Yorkshire Council Waste Tranfer 15 Jun 2017 **Process: 7821** Controlled Waste Description And Transfer 15 Jun 2017 **Process: 7835** Electrics Need Checking 20 Sep 2017 **Process: 7836** Central Heating For Winter 20 Sep 2017 **Process: 7713** Review Roles And Responsibilitys 17 Aug 2016 **Process: 7845** 7.1.4 Environment Of Operations 25 Sep 2017 **Process: 45** Responsibility Allocation : Main Server Status 16 Feb 2016 **Process: 48** Responsibility Allocation : Internet 16 Feb 2016 **Process: 52** Software Verification Clear Down Backup Emails 16 Feb 2016 **Process: 5903** Responsibility Allocation : Weather Station 02 Mar 2016 **Process: 5939** Responsibility Allocation : Email ISP Routing 05 Mar 2016 **Process: 7121** Responsibility Allocation : General Computer Maintenance 09 Mar 2016 **Process: 7129** Intrastats Cross Reference Database Tables Updates 09 Mar 2016 **Process: 7672** Off Site Backup 09 Mar 2016 **Process: 7704** Responsibility Allocation : Computer Failure

	Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document ID21806 Date Revision 05 Sep 2017 Reviewed 05 Sep 2017 **Audit 15 Production** Revision Document ID17384 Date Revision 03 Sep 2016 Reviewed 03 Sep 2016	Diagnostics 24 May 2016 **Process: 7850** Software Validation Scan In Correct Product 01 Oct 2017 **Process: 7851** Software Validation Scan Un-QA Product To Order 01 Oct 2017 **Process: 7852** Software Validation Expired Stock 01 Oct 2017 **Process: 7853** Software Validation Non Sell Able Shelf 01 Oct 2017 **Process: 7854** Software Validation In Production List 01 Oct 2017 **Process: 7855** Software Validation - Production Lists 01 Oct 2017 **Process: 7856** Software Validation Unchecked Orders 01 Oct 2017 **Process: 7857** Software Validation Stock Tracking Check 01 Oct 2017 **Process: 7858** Software Validation Attempt To QA Some Stock 01 Oct 2017 **Process: 7861** Software Validation Of Training Documents Forced Reading 03 Oct 2017
6.4 Work environment and contamination control **Work environment and contamination control**		
6.4.1 The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such	**Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure** Revision Document ID8672 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **CPM 15 Disciplinary Procedures** Revision Document ID8360 Date Revision 07 Jun 2011 Reviewed 07 Jun 2011 **CPM 16 Dress Code** Revision Document ID7055 Date Revision 26 Apr 2010 Reviewed 22 Jul 2014 **CPM 25 Health and Safety Policy Viamed** Revision Document ID14332 Date Revision 25 Sep 2014 Reviewed 04 Sep 2017 **CPM 39 Smoking Policy**	**Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016 **Process: 7720** Audit 08 Training Viamed 24 Aug 2016 **Process: 7729** Audit 19 Health And Saftey Viamed 24 Aug 2016 **Process: 56** Warehouse Outside Heating Guard 17 Feb 2016 **Process: 5919** Check Out Side Drain 05 Mar 2016 **Process: 5921** Clearing Water Downstairs 05 Mar 2016 **Process: 7120** General Maintenance Requirements 09 Mar 2016 **Process: 7742** Boiler Check 26 Sep 2016 **Process: 7756** Carbon Monoxide Alarm 05 Jan 2017

personnel and the product or work environment could affect medical device safety or performance; b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person. NOTE Further information can be found in ISO 14644 and ISO 14698 **Work environment**	Revision Document ID6782 Date Revision 15 Feb 2010 Reviewed 15 Feb 2010 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 08 Training, Competence and Human Resources** Revision Document ID9033 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document ID21806 Date Revision 05 Sep 2017 Reviewed 05 Sep 2017	**Process: 7820** North Yorkshire Council Waste Tranfer 15 Jun 2017 **Process: 7821** Controlled Waste Description And Transfer 15 Jun 2017 **Process: 7835** Electrics Need Checking 20 Sep 2017 **Process: 7836** Central Heating For Winter 20 Sep 2017 **Process: 7864** ESD Work Stations 07 Oct 2017 **Process: 7873** On Site Environment Review 18 Oct 2017 **Process: 54** Responsibility Allocation : Gents Toilets 17 Feb 2016 **Process: 5906** Empty Paper Bins 03 Mar 2016 **Process: 5907** Hoover Warehouse 03 Mar 2016 **Process: 5908** Sweep Warehouse 03 Mar 2016 **Process: 5909** Empty Warehouse Bins 03 Mar 2016 **Process: 5910** Clean Duckets 03 Mar 2016 **Process: 5911** Responsibility Allocation : Clear Cardboard 03 Mar 2016 **Process: 7698** Clean Toilets 17 May 2016
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**	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017 **Viamed Environment Policy Inc WEEE** Revision Document ID17472 Date Revision 14 Sep 2016 Reviewed 30 Sep 2017 **Wee Registration Viamed** Revision Document ID13264 Date Revision 09 Jan 2014 Reviewed 09 Jan 2014 **Wee Registration Vandagraph** Revision Document ID13265 Date Revision 09 Jan 2014 Reviewed 09 Jan 2014	**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

	Audit 07 Handling and Storage Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 01 Picking packing** Revision Document ID7664 Date Revision 14 Feb 2011 Reviewed 14 Feb 2011 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document ID21806 Date Revision 05 Sep 2017 Reviewed 05 Sep 2017	

7 Product realization

7 **Product realization**		
7.1 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	**VM3COP24.00 Viamed Overall Risk Analysis Program** Revision Document ID23006 Date Revision 19 Oct 2017 Reviewed 19 Oct 2017 **VM3COP27.12 Clinical Evaluation Risk assessment Technical Files** Revision Document ID15453 Date Revision 11 Aug 2015 Reviewed 11 Aug 2015 **VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document ID17824 Date Revision 03 Nov 2016 Reviewed 03 Nov 2016 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 03 Design Control**	**Process: 7732** Audit 22 Post Market Survellance Viamed 24 Aug 2016 **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016

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. **Planning of product realization**	Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	
7.2 **Customer-related processes**		
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**	**Top Level Document: VOP 14 Servicing Out of Building Servicing** Revision Document ID8669 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Top Level Document: VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** Revision Document ID22950 Date Revision 18 Oct 2017 Reviewed 18 Oct 2017 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 02 Contract Review and Sales Order Processing** Revision Document ID17280 Date Revision 16 Aug 2016 Reviewed 16 Aug	**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** 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** Checking Of Sales Orders 16 Feb 2016 **Process: 7734** Humanmed Order Processing 25 Aug 2016 **Process: 5** Processing Of Sales Orders 16 Feb 2016 **Process: 7734** Humanmed Order Processing 25 Aug 2016

	2016 **VM3COP20.31 Export Order Processing** Revision Document ID22016 Date Revision 15 Sep 2017 Reviewed 15 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 ID22527 Date Revision 11 Oct 2017 Reviewed 11 Oct 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 ID22369 Date Revision 29 Sep 2017 Reviewed 29 Sep 2017 **VM3COP20.32 Order Checking** Revision Document ID17152 Date Revision 05 Jul 2016 Reviewed 05 Jul 2016 **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	**Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017

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 **VM3COPxx Viamed Policy on End User Training UK** Revision Document ID9289 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 01 Picking packing** Revision Document ID7664 Date Revision 14 Feb 2011 Reviewed 14 Feb 2011 **Audit 16 Sales and Marketing** Revision Document ID22080 Date Revision 17 Sep 2017 Reviewed 17 Sep 2017	
7.2.2 The organization shall review the requirements related to product. This review shall be conducted	**Audit 02 Contract Review and Sales Order Processing** Revision Document ID17280 Date Revision 16	**Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016 **Process: 7724** Audit 11 Repairs And Service Viamed 24 Aug

prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that: a) product requirements are defined and documented; b) contract or order requirements differing from those previously expressed are resolved; c) applicable regulatory requirements are met; d) any user training identified in accordance with 7.2.1 is available or planned to be available; e) the organization has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5). When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. **Review of requirements related to product**	Aug 2016 Reviewed 16 Aug 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document ID17321 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 16 Sales and Marketing** Revision Document ID22080 Date Revision 17 Sep 2017 Reviewed 17 Sep 2017	2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016
7.2.3 The organization shall plan and document arrangements for communicating with customers in relation to: a) product information; b) enquiries, contracts or order handling, including amendments; c) customer feedback, including complaints; d) advisory notices. The organization shall	**Top Level Document: VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** Revision Document ID22950 Date Revision 18 Oct 2017 Reviewed 18 Oct 2017 **Top Level Document: vop VM3COP20.11 Non-Conformances** Revision Document ID21314 Date Revision 06 Aug 2017 Reviewed 06 Aug	**Process: 2** Answering Telephones 16 Feb 2016 **Process: 7710** Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017 **Process: 6828** Non Conformance Issues 09 Mar 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016

communicate with regulatory authorities in accordance with applicable regulatory requirements. **Communication**	2017 **Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document ID17419 Date Revision 06 Sep 2016 Reviewed 06 Sep 2016 **VM3COP27.31 Processing Proforma Invoices and Quotations** Revision Document ID20584 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **VM3COP20.05 New Orders - How to enter into Opera Viamed** Revision Document ID13695 Date Revision 12 May 2014 Reviewed 12 May 2014 **VM3COP20.32 Order Checking** Revision Document ID17152 Date Revision 05 Jul 2016 Reviewed 05 Jul 2016 **VM3COP20.49 Informing Customers of Price Amends** Revision Document ID18357 Date Revision 05 Jan 2017 Reviewed 05 Jan 2017 **VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork** Revision Document ID13968 Date Revision 23 May 2014 Reviewed 23 May 2014 **VM3COP20.22 Quoting Customer Special prices.** Revision Document ID15613 Date Revision 09 Sep 2015 Reviewed 09 Sep 2015 **VM3COP10.02 Product Recall locate products out in the Field** Revision Document ID13158 Date Revision 14 Nov 2013 Reviewed 14 Nov	**Process: 7726** Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016

	2013 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 02 Contract Review and Sales Order Processing** Revision Document ID17280 Date Revision 16 Aug 2016 Reviewed 16 Aug 2016 **Audit 16 Sales and Marketing** Revision Document ID22080 Date Revision 17 Sep 2017 Reviewed 17 Sep 2017 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 01 Picking packing** Revision Document ID7664 Date Revision 14 Feb 2011 Reviewed 14 Feb 2011 **Audit 04 Accounts and Finance** Revision Document ID22086 Date Revision 17 Sep 2017 Reviewed 17 Sep 2017	
7.3 **Design and development**		
7.3.1 The organization shall document procedures for design and development **General**	**Top Level Document: VOP 17 Design Research and Development** Revision Document ID9182 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **BSI Technical File Design File Requirements Dosier** Revision Document ID4959 Date Revision 29 Dec 2008	**Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017

	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** Revision Document ID7396 Date Revision 10 Jan 2011 Reviewed 10 Jan 2011 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	
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	**VM3COP16 Design and Design Changes** Revision Document ID7396 Date Revision 10 Jan 2011 Reviewed 10 Jan 2011 **VM3COP27.07 Project Manager** Revision Document ID12734 Date Revision 11 Jul 2013 Reviewed 11 Jul 2013 **VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document ID17824 Date Revision 03 Nov 2016 Reviewed 03 Nov 2016 **VM3COP27.12 Clinical Evaluation Risk assessment Technical Files** Revision Document	**Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7720** Audit 08 Training Viamed 24 Aug 2016

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**	ID15453 Date Revision 11 Aug 2015 Reviewed 11 Aug 2015 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 08 Training, Competence and Human Resources** Revision Document ID9033 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	
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–	**Top Level Document: VOP 17 Design Research and Development** Revision Document ID9182 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	**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 21 Oct 2017

1. **Design and development inputs**		
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; 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**	**Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 05 Purchasing suppliers** Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016
7.3.5 **Design and development review**	**Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	
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	**Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016

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).		
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**	**Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	
7.3.7 **Design and development validation**	**Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	
7.3.7 Design and development validation shall be performed in accordance with planned and	**Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016	**Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017

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).	**Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 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**	**Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016
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**	**Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	**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**	**Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 12 CE Files** Revision Document ID17299 Date Revision 19 Aug 2016 Reviewed 19 Aug 2016	**Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016
7.4 **Purchasing**	**VM3COP04 Purchasing / suppliers** Revision Document ID15473 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015 **VM3COP20.29 Checking the Purchase Order Log** Revision Document ID20588 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **VM3COP27.34 Sending Purchase Orders to Suppliers** Revision Document ID17070 Date Revision 22 Jun 2016 Reviewed 22 Jun 2016 **VM3COP04.01 QC06 Supplier Questionnaire ISO Questionnaire Viamed Blank** Revision Document ID21304 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017	**Process: 5850** Purchase Order Log 17 Feb 2016 **Process: 7707** Send Purchase Orders To Suppliers 13 Jun 2016
7.4.1 The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a) based on the supplier’s ability to provide product	**Audit 05 Purchasing suppliers** Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 04 Accounts and Finance** Revision Document	**Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 **Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016

that meets the organizations' requirements; b) based on the performance of the supplier; c) based on the effect of the purchased product on the quality of the medical device; d) proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5). **Purchasing process**	ID22086 Date Revision 17 Sep 2017 Reviewed 17 Sep 2017	
7.4.2 Purchasing information shall describe or reference the product to be purchased, including as appropriate: a) product specifications; b) requirements for product acceptance, procedures, processes and equipment; c) requirements for qualification of supplier personnel; d) quality management system requirements. The organization shall ensure the adequacy of specified purchasing requirements prior to their	**Audit 05 Purchasing suppliers** Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	**Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016

communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5). **Purchasing information**		
7.4.3 The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.5). **Verification of purchased product**	**Audit 05 Purchasing suppliers** Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016	**Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016

7.5 **Production and service provision**		
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**	**VM3COP20.37 Generating a New Service Visit** Revision Document ID17116 Date Revision 28 Jun 2016 Reviewed 28 Jun 2016 **Audit 06 Calibration** Revision Document ID17282 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 01 Picking packing** Revision Document ID7664 Date Revision 14 Feb 2011 Reviewed 14 Feb 2011 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 15 Production** Revision Document ID17384 Date Revision 03 Sep 2016 Reviewed 03 Sep 2016 **Audit 24 Service Logs** Revision Document ID14795 Date Revision 20 Feb 2015 Reviewed 20 Feb 2015 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016	**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
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-	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017 **Audit 05 Purchasing suppliers**	**Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 **Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016

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**	Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 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**	**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 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 05 Purchasing suppliers** Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016	**Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016

	Audit 24 Service Logs Revision Document ID14795 Date Revision 20 Feb 2015 Reviewed 20 Feb 2015	
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**	**VM3COP20.27 Annual Services for Resuscitation Cabinets** Revision Document ID16987 Date Revision 25 May 2016 Reviewed 25 May 2016 **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 **VM3COP50.13 Quality Control Tom Thumb** Revision Document ID15365 Date Revision 05 Aug 2015 Reviewed 05 Aug 2015 **Audit 24 Service Logs** Revision Document ID14795 Date Revision 20 Feb 2015 Reviewed 20 Feb 2015 **Audit 11 Repairs, Servicing and Returns** Revision Document ID17321 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	**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	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document	**Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7717**

sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices. **Particular requirements for sterile medical devices**	ID22838 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017	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	**VM3COP18 Post Market Surveilance** Revision Document ID8106 Date Revision 21 Mar 2011 Reviewed 21 Mar 2011 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 24 Service Logs** Revision Document ID14795 Date Revision 20 Feb 2015 Reviewed 20 Feb 2015 **Audit 11 Repairs, Servicing and Returns** Revision Document ID17321 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	

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**		
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**	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017	
7.5.8 The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization.	**Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document ID13387 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24	

Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product. **Identification**	Aug 2016 Reviewed 24 Aug 2016 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document ID17321 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	
7.5.9 **Traceability**	**VM3COP14.01 Disposition of Documents / Records.** Revision Document ID15464 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015	
7.5.9.1 The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5). **General**	**VM3COP14.01 Disposition of Documents / Records.** Revision Document ID15464 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015 **VM3COP23.00 EAN13 Barcodes to Stock and the Online Databases** Revision Document ID8596 Date Revision 25 Aug 2011 Reviewed 25 Aug 2011 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 10 Documentation Control** Revision Document	

	ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	
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 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**	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document ID22838 Date Revision 16 Oct 2017 Reviewed 16 Oct 2017	
7.5.10 The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5). **Customer property**	**VM3COP09 Repairs** Revision Document ID8712 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **VM3COP20.03 Repair Procedures** Revision Document ID13703 Date Revision 13 May 2014 Reviewed 13 May 2014 **VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork** Revision Document ID13968 Date Revision 23 May 2014 Reviewed 23 May 2014 **VM3COP20.47 Collecting Repair Paperwork** Revision Document ID17485 Date Revision 15 Sep 2016 Reviewed 15 Sep 2016 **Audit 07 Handling and Storage** Revision Document	**Process: 7684** Repairs Ready For Quote 18 Apr 2016 **Process: 7685** Repairs Ready For Invoice 18 Apr 2016 **Process: 5891** Processing Of Repair Quotes And Orders 25 Feb 2016 **Process: 7693** Collect Repair Filing From Warehouse 22 Apr 2016

	ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document ID17321 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	
7.5.11 The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5). **Preservation of product**	**VM3COP20.03 Repair Procedures** Revision Document ID13703 Date Revision 13 May 2014 Reviewed 13 May 2014 **VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork** Revision Document ID13968 Date Revision 23 May 2014 Reviewed 23 May 2014 **Audit 01 Picking packing** Revision Document ID7664 Date Revision 14 Feb 2011 Reviewed 14 Feb 2011 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	**Process: 7684** Repairs Ready For Quote 18 Apr 2016 **Process: 7685** Repairs Ready For Invoice 18 Apr 2016 **Process: 5891** Processing Of Repair Quotes And Orders 25 Feb 2016
7.6 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to	**Top Level Document: VOP 06 Measurement Control VST, Calibration, QA Stock** Revision Document ID13385 Date Revision 28 Mar 2014 Reviewed 28 Mar 2014 **Top Level Document: VOP**	

determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5); b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5); c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product	**06 Measurement Control Viamed, Calibration, QA Stock** Revision Document ID6268 Date Revision 06 Aug 2009 Reviewed 06 Aug 2009 **VM3COP11 Calibration** Revision Document ID8713 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Explanation Control of documents** Revision Document ID21322 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 **Audit 06 Calibration** Revision Document ID17282 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017		

affected. Records of the results of calibration and verification shall be maintained (see 4.2.5). The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. 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). NOTE Further information can be found in ISO 10012. **Control of monitoring and measuring equipment**		

8 Measurement, analysis and improvement

8 **Measurement, analysis and improvement**		
8.1 The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to: a) demonstrate conformity of product; b) ensure conformity of the quality management system; c) maintain the effectiveness of the quality management system.	**Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 **VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document ID17824 Date Revision 03 Nov 2016 Reviewed 03 Nov 2016	**Process: 7714** Audit 01 Picking Packing Viamed 24 Aug 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016 **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 **Process: 7718** Audit 06 Calibration Viamed 24 Aug 2016

This shall include determination of appropriate methods, including statistical techniques, and the extent of their use. **General**	**Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **VM3COP13 Audits** Revision Document ID8715 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011	**Process: 7720** Audit 08 Training Viamed 24 Aug 2016 **Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016 **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7724** Audit 11 Repairs And Service Viamed 24 Aug 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016 **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 **Process: 7727** Audit 15 Production Viamed 24 Aug 2016 **Process: 7728** Audit 17 Internal Audits Viamed 24 Aug 2016 **Process: 7729** Audit 19 Health And Saftey Viamed 24 Aug 2016 **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 7731** Audit 21 Audit Of Audit Viamed 24 Aug 2016 **Process: 7732** Audit 22 Post Market Survellance Viamed 24 Aug 2016 **Process: 7733** Audit 23 Analysis Of Data Viamed 24 Aug 2016
8.2 **Monitoring and measurement**		
8.2.1 As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented. The organization shall	**VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document ID17824 Date Revision 03 Nov 2016 Reviewed 03 Nov 2016 **Management Review** Revision Document ID19792 Date Revision 05 May 2017 Reviewed 05 May 2017 **Management reviews** Revision Document	

document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process. **Feedback**	ID19801 Date Revision 05 May 2017 Reviewed 05 May 2017 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	
8.2.2 The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for: a) receiving and recording information; b) evaluating information to determine if the feedback constitutes a complaint; c) investigating complaints; d) determining the need to report the information to the appropriate regulatory authorities; e) handling of complaint-related product; f) determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document ID17419 Date Revision 06 Sep 2016 Reviewed 06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document ID13697 Date Revision 12 May 2014 Reviewed 12 May 2014 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	**Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016

determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Complaint handling records shall be maintained (see 4.2.5). **Complaint handling**		
8.2.3 If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.5). **Reporting to regulatory authorities**	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document ID17419 Date Revision 06 Sep 2016 Reviewed 06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document ID13697 Date Revision 12 May 2014 Reviewed 12 May 2014 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **MHRA Correspondence / RG2 Devices list** Revision Document ID14763 Date Revision 12 Feb 2015 Reviewed 12 Feb 2015 **MHRA Appendix A / Appendix B Class 1 Device Codes** Revision Document ID4798 Date Revision 24 Oct 2008 Reviewed 24 Oct 2008 **CE Guidance 19 Own Brand MHRA position obl** Revision Document ID3656 Date Revision 29 Apr 2008 Reviewed 29 Apr 2008	**Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016
8.2.4 The organization shall conduct internal audits at planned intervals to determine whether the quality	**Audit 01 Picking packing** Revision Document ID7664 Date Revision 14 Feb 2011 Reviewed 14 Feb 2011 **Audit 02 Contract Review and Sales Order**	**Process: 7714** Audit 01 Picking Packing Viamed 24 Aug 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016

management system:
a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable
regulatory requirements;
b) is effectively implemented and maintained.
The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.
An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
Records of the audits and their results, including identification of the processes and areas audited and
the conclusions, shall be maintained (see 4.2.5).
The management responsible for the area being audited shall ensure that any necessary corrections
and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.
NOTE Further information

Processing
Revision Document ID17280 Date Revision 16 Aug 2016 Reviewed 16 Aug 2016
Audit 03 Design Control
Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016
Audit 05 Purchasing suppliers
Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016
Audit 06 Calibration
Revision Document ID17282 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016
Audit 07 Handling and Storage
Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016
Audit 08 Training, Competence and Human Resources
Revision Document ID9033 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011
Audit 09 Goods Inward and Product Identity
Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016
Audit 10 Documentation Control
Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016
Audit 10b Process Verification
Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016
Audit 11 Repairs, Servicing and Returns
Revision Document ID17321 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016
Audit 14 Complaints and

Process: 7716
Audit 03 Design Control Viamed 24 Aug 2016
Process: 7717
Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
Process: 7718
Audit 06 Calibration Viamed 24 Aug 2016
Process: 7719
Audit 07 Handling And Storage Viamed 24 Aug 2016
Process: 7720
Audit 08 Training Viamed 24 Aug 2016
Process: 7721
Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016
Process: 7722
Audit 10 Documentation Control Viamed 24 Aug 2016
Process: 7723
Audit 10b Process Verification Viamed 21 Oct 2017
Process: 7725
Audit 12 CE Files Viamed 24 Aug 2016
Process: 7724
Audit 11 Repairs And Service Viamed 24 Aug 2016
Process: 7726
Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016
Process: 7727
Audit 15 Production Viamed 24 Aug 2016
Process: 7728
Audit 17 Internal Audits Viamed 24 Aug 2016
Process: 7729
Audit 19 Health And Saftey Viamed 24 Aug 2016
Process: 7730
Audit 20 Process Verification To Managment Viamed 24 Aug 2016
Process: 7731
Audit 21 Audit Of Audit Viamed 24 Aug 2016
Process: 7732
Audit 22 Post Market Survellance Viamed 24 Aug 2016
Process: 7733
Audit 23 Analysis Of Data Viamed 24 Aug 2016

can be found in ISO 19011. **Internal audit**	**Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 15 Production** Revision Document ID17384 Date Revision 03 Sep 2016 Reviewed 03 Sep 2016 **Audit 17 Internal Audits** Revision Document ID8798 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document ID21806 Date Revision 05 Sep 2017 Reviewed 05 Sep 2017 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Audit 21 Audit of Audit** Revision Document ID9037 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 24 Service Logs** Revision Document ID14795 Date Revision 20 Feb 2015 Reviewed 20 Feb 2015 **Explanation Employee Roles and Titles** Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017		

	VM3COP13 Audits Revision Document ID8715 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Audit Schedule** Revision Document ID13027 Date Revision 21 Jan 2013 Reviewed 21 Jan 2013 **Audit 04 Accounts and Finance** Revision Document ID22086 Date Revision 17 Sep 2017 Reviewed 17 Sep 2017	
8.2.5 The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. **Monitoring and measurement of processes**	**Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	
8.2.6 The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures. Evidence of conformity with the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities. Product release and service	**VM3COP11 Calibration** Revision Document ID8713 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **VM3COP29 Production** Revision Document ID8727 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 15 Production** Revision Document ID17384 Date Revision 03 Sep 2016 Reviewed 03 Sep 2016	

delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed. For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing. **Monitoring and measurement of product**		
8.3 **Control of nonconforming product**		
8.3.1 The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5) **General**	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document ID17419 Date Revision 06 Sep 2016 Reviewed 06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document ID13697 Date Revision 12 May 2014 Reviewed 12 May 2014 **Top Level Document: vop VM3COP20.11 Non-Conformances** Revision Document ID21314 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 **VM3COP10.02 Product Recall locate products out in the Field** Revision Document ID13158 Date Revision 14 Nov 2013 Reviewed 14 Nov 2013 **Issues Overview** Revision Document ID22272 Date Revision 27 Sep 2017 Reviewed 27 Sep 2017 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24	**Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 6828** Non Conformance Issues 09 Mar 2016

	Aug 2016 Reviewed 24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document ID17395 Date Revision 05 Sep 2016 Reviewed 05 Sep 2016 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	
8.3.2 The organization shall deal with nonconforming product by one or more of the following ways: a) taking action to eliminate the detected nonconformity; b) taking action to preclude its original intended use or application; c) authorizing its use, release or acceptance under concession. The organization shall ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5). **Actions in response to nonconforming product detected before delivery**	**Top Level Document: vop VM3COP20.11 Non-Conformances** Revision Document ID21314 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 07 Handling and Storage** Revision Document ID17316 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016	
8.3.3 When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5). The organization shall document procedures for issuing advisory notices in	**Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	

accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5). **Actions in response to nonconforming product detected after delivery**		
8.3.4 The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained (see 4.2.5). **Rework**	**Top Level Document: VOP 09 Repairs External and Internal Repairs** Revision Document ID6271 Date Revision 06 Aug 2009 Reviewed 06 Aug 2009 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Audit 11 Repairs, Servicing and Returns** Revision Document ID17321 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016	
8.4 The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback;	**Top Level Document: VOP 13 Process Monitoring, System Reviews, Audits, Management Review** Revision Document ID22946 Date Revision 18 Oct 2017 Reviewed 18 Oct 2017 **Audit 05 Purchasing suppliers** Revision Document ID17284 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 17 Internal Audits** Revision Document ID8798 Date Revision 12 Oct 2011	

b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5). **Analysis of data**	Reviewed 12 Oct 2011 **Audit 22 Post Market Survellance** Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 24 Service Logs** Revision Document ID14795 Date Revision 20 Feb 2015 Reviewed 20 Feb 2015	
8.5 **Improvement**		
8.5.1 The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review. **General**	**Top Level Document: VOP10.01 VM3COP10.01 Preventative Actions** Revision Document ID22462 Date Revision 05 Oct 2017 Reviewed 05 Oct 2017 **Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document ID6275 Date Revision 06 Aug 2009 Reviewed 06 Aug 2009 **Audit 03 Design Control** Revision Document ID15552 Date Revision 25 Aug 2015 Reviewed 07 Sep 2016 **Audit 06 Calibration** Revision Document ID17282 Date Revision 17 Aug 2016 Reviewed 17 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 18 Management Review Blank** Revision Document ID20565 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017	

	Audit 22 Post Market Survellance Revision Document ID9386 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 **Audit 23 Analysis of Data** Revision Document ID20567 Date Revision 12 Jun 2017 Reviewed 12 Jun 2017 **Audit 21 Audit of Audit** Revision Document ID9037 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	
8.5.2 The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; f) reviewing the effectiveness of corrective action taken Records of the results of any investigation and action	**Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document ID6275 Date Revision 06 Aug 2009 Reviewed 06 Aug 2009 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 10 Documentation Control** Revision Document ID17324 Date Revision 24 Aug 2016 Reviewed 24 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	

taken shall be maintained (see 4.2.5). **Corrective action**		
8.5.3 The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; e) reviewing the effectiveness of the preventive action taken, as appropriate. Records of the results of any investigations and of action taken shall be maintained (see 4.2.5). **Preventive action**	**Top Level Document: VOP10.01 VM3COP10.01 Preventative Actions** Revision Document ID22462 Date Revision 05 Oct 2017 Reviewed 05 Oct 2017 **Audit 20 Process verification to Managment** Revision Document ID20569 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 **Audit 10b Process Verification** Revision Document ID17350 Date Revision 31 Aug 2016 Reviewed 31 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document ID9273 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011	**Process: 7839** Review VIAMED Feedback - Customer Complaints 23 Sep 2017

Document ID	Sub Processes
ID17324	**Audit 10 Documentation Control** **Process: 10** Distribution Of Emails 16 Feb 2016 **Process: 5939** Responsibility Allocation : Email ISP Routing 05 Mar 2016 **Process: 5940** Thumb Nail Processor 07 Mar 2016 **Process: 11** Distribution Of Mail 16 Feb 2016 **Process: 6** Updating Contact Management System 16 Feb 2016 **Process: 5901** Link Call Log Contacts To The CRM 02 Mar 2016 **Process: 52** Software Verification Clear Down Backup Emails 16 Feb 2016

	Process: 53 Emails 16 Feb 2016 **Process: 7672** Off Site Backup 09 Mar 2016 **Process: 7700** Domain Name Management 19 May 2016 **Process: 9** Distribution Of Faxes 16 Feb 2016 **Process: 15** Filing and Archiving 16 Feb 2016 **Process: 7711** Import Bank CSV 01 Jul 2016 **Process: 7722** Audit 10 Documentation Control Viamed 24 Aug 2016 **Process: 7693** Collect Repair Filing From Warehouse 22 Apr 2016 **Process: 12** Sales And Technical Information Processing 16 Feb 2016 **Process: 16** Responsibility Allocation : Photocopying 16 Feb 2016 **Process: 7699** Shred Sensitive Paperwork In JL Office 19 May 2016 **Process: 7705** Checking For Uploaded Files 08 Jun 2016 **Process: 7754** Ensure Procedures Are Up-to-date 24 Nov 2016 **Process: 7770** Audit 10 Documentation Control VST 08 Feb 2017 **Process: 6938** Customer Database Updates 09 Mar 2016 **Process: 6940** Responsibility Allocation : Customer Ongoing task List 09 Mar 2016 **Process: 7090** Responsibility Allocation : Office Procedures 09 Mar 2016 **Process: 7032** Document Requirements 09 Mar 2016 **Process: 41** Responsibility Allocation : Documentation Control 16 Feb 2016 **Process: 59** Out Of Date Documents 17 Feb 2016 **Process: 5851** Duplicate Documents 17 Feb 2016 **Process: 5852** Responsibility Allocation : Retention Of Records 17 Feb 2016 **Process: 7124** Responsibility Allocation : Intrastats 09 Mar 2016 **Process: 7125** Responsibility Allocation : Intrastats Urgent Problems 09 Mar 2016 **Process: 7126** Intrastats Requested Page updates 09 Mar 2016 **Process: 7127** Responsibility Allocation : Intrastats Unfinished in progress Processes 09 Mar 2016 **Process: 7128** Responsibility Allocation : Intrastats Future Features needed 09 Mar 2016 **Process: 7129** Intrastats Cross Reference Database Tables Updates 09 Mar 2016 **Process: 7130** Intrastats Information for Intrastats and L Drive 09 Mar 2016 **Process: 7131** Responsibility Allocation : Intrastats Opera 09 Mar 2016 **Process: 7133** Responsibility Allocation : Intrastats Contact Manager 09 Mar 2016 **Process: 7739** Intrastats Amendment Log 12 Sep 2016 **Process: 5877** Responsibility Allocation : Review Company Data 17 Feb 2016 **Process: 44** Secure Socket Level Certificate 16 Feb 2016 **Process: 5890** Check Website ISO Documents 24 Feb 2016 **Process: 7863** Maintain Repair Codes List 05 Oct 2017
ID20565	**Audit 18 Management Review Blank** **Process: 55** Business Continuity Plan 17 Feb 2016 **Process: 23** Company Objectives 16 Feb 2016 **Process: 6813** Management Meeting Turnover Report 09 Mar 2016 **Process: 27** Management Reviews And Quality Audits 16 Feb 2016 **Process: 22** Company Policys 16 Feb 2016 **Process: 7750** Meeting With Management 14 Oct 2016 **Process: 7793** Team Review Meeting 16 Mar 2017 **Process: 7753** Management Meeting 22 Nov 2016 **Process: 6861** Management Meeting Review Weekly Meeting 09 Mar 2016 **Process: 7833** Importance Of Effective Quality Management 20 Sep 2017 **Process: 7834** Financial Review 20 Sep 2017 **Process: 26** Company Resources 16 Feb 2016 **Process: 29** Responsibility Allocation : CMDCAS Updates And Licences 16 Feb 2016 **Process: 5889** Responsibility Allocation : Audit And Task - Audit 24 Feb 2016 **Process: 7744** FDA Device Establishment Registration And Listing 28 Sep 2016 **Process: 7829** Complete Systems Review 17 Sep 2017 **Process: 6871** ISO14001 Environmental management systems 09 Mar 2016 **Process: 7862** Review The Audit Calender Screen 04 Oct 2017
ID13377	**VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision**

	control **Process: 5940** Thumb Nail Processor 07 Mar 2016 **Process: 7827** Review The Quality Policy VST 16 Sep 2017 **Process: 7828** Review The Quality Policy Viamed 16 Sep 2017 **Process: 5934** Responsibility Allocation : Staff Training 05 Mar 2016 **Process: 7032** Document Requirements 09 Mar 2016 **Process: 41** Responsibility Allocation : Documentation Control 16 Feb 2016 **Process: 59** Out Of Date Documents 17 Feb 2016 **Process: 5851** Duplicate Documents 17 Feb 2016 **Process: 5852** Responsibility Allocation : Retention Of Records 17 Feb 2016 **Process: 7130** Intrastats Information for Intrastats and L Drive 09 Mar 2016 **Process: 5890** Check Website ISO Documents 24 Feb 2016 **Process: 7200** Responsibility Allocation : ISO Issues 09 Mar 2016 **Process: 7744** FDA Device Establishment Registration And Listing 28 Sep 2016
ID22645	**Viamed ISO 13485:2016 Scope** **Process: 7848** Review ISO Scopes 27 Sep 2017
ID8700	**Chart 27 Customer Complaints Chart 27** **Process: 7743** Customer Complaints Paper File 26 Sep 2016
ID17350	**Audit 10b Process Verification** **Process: 7701** AWS Amazon Web Services 23 May 2016 **Process: 7723** Audit 10b Process Verification Viamed 21 Oct 2017 **Process: 7827** Review The Quality Policy VST 16 Sep 2017 **Process: 7828** Review The Quality Policy Viamed 16 Sep 2017 **Process: 7771** Audit 10b Process Verification VST 08 Feb 2017 **Process: 6866** Internal Process Verification Complete Systems Review 09 Mar 2016 **Process: 7755** Fast Hosts Invoice 08 Dec 2016 **Process: 7845** 7.1.4 Environment Of Operations 25 Sep 2017 **Process: 7846** ISO System Management Review 26 Sep 2017 **Process: 7837** Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 **Process: 7832** Cleardown Emailed Invoices 20 Sep 2017 **Process: 7848** Review ISO Scopes 27 Sep 2017 **Process: 7851** Software Validation Scan Un-QA Product To Order 01 Oct 2017 **Process: 7852** Software Validation Expired Stock 01 Oct 2017 **Process: 7853** Software Validation Non Sell Able Shelf 01 Oct 2017 **Process: 7854** Software Validation In Production List 01 Oct 2017 **Process: 7855** Software Validation - Production Lists 01 Oct 2017 **Process: 7856** Software Validation Unchecked Orders 01 Oct 2017 **Process: 7857** Software Validation Stock Tracking Check 01 Oct 2017 **Process: 7858** Software Validation Attempt To QA Some Stock 01 Oct 2017 **Process: 7861** Software Validation Of Training Documents Forced Reading 03 Oct 2017 **Process: 7850** Software Validation Scan In Correct Product 01 Oct 2017 **Process: 7871** Review Exclusion From Viamed 13485:2016 And VST 9001:2015 15 Oct 2017 **Process: 7865** Software Validation Conflicting Audits 07 Oct 2017 **Process: 7870** Software Validation Non Conformance Product Risk Feedback Loop 15 Oct 2017
ID16995	**VM3COP27.17 Complete Auto_calender Issues** **Process: 27** Management Reviews And Quality Audits 16 Feb 2016
ID20131	**VM3COP27.02 Collecting Emails and Distributing** **Process: 10** Distribution Of Emails 16 Feb 2016
ID20569	**Audit 20 Process verification to Managment** **Process: 7730** Audit 20 Process Verification To Managment Viamed 24 Aug 2016 **Process: 7778** Audit 20 Process Verification To Managment VST 08 Feb 2017
ID13387	**VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** **Process: 6973** Responsibility Allocation : Stock Transfers. (QC19) 09 Mar 2016 **Process: 7675** Responsibility Allocation : Ordering Demo Stock For Humanmed Reps 11 Mar

	2016 **Process: 5872** Check Sale Or Returns Export 17 Feb 2016 **Process: 5871** Check Sale Or Returns 17 Feb 2016 **Process: 5855** Purchase Order Requirements Teledyne 17 Feb 2016 **Process: 5858** Opera Stock Adjustments 17 Feb 2016 **Process: 5868** Return Goods To Suppliers 17 Feb 2016 **Process: 5935** Stock Allocations 05 Mar 2016 **Process: 6829** Supplier Review - Outstanding orders 09 Mar 2016 **Process: 6832** Supplier Review Future orders 09 Mar 2016 **Process: 6840** Minimum Stock Report 09 Mar 2016 **Process: 6848** Returns Stock Report 09 Mar 2016 **Process: 6850** Current Stock Levels 09 Mar 2016 **Process: 6945** Missing Stock or Adjustments 09 Mar 2016 **Process: 6955** Production Requirements 09 Mar 2016 **Process: 7046** Stock Purchasing 09 Mar 2016 **Process: 7051** Responsibility Allocation : Control of nonconforming product 09 Mar 2016 **Process: 7673** Check Expiry Dated Stock 09 Mar 2016 **Process: 7679** Check Stock Requirements Supplier Teledyne 18 Apr 2016 **Process: 7680** Check Stock Requirements Supplier Envitec 18 Apr 2016 **Process: 7681** Check Stock Requirements Supplier Posey 18 Apr 2016 **Process: 7682** Check Stock Requirements Supplier Bluepoint 18 Apr 2016 **Process: 7687** Vandagraph Duckets 21 Apr 2016 **Process: 7688** Move Stock From QA Shelf To Stock Shelf Friday 21 Apr 2016 **Process: 7689** Move Stock From QA Shelf To Stock Shelf Monday 21 Apr 2016 **Process: 7694** Move Stock From QA Shelf To Stock Shelf Tuesday 28 Apr 2016 **Process: 7695** Top Up Quick Shipping Shelves 28 Apr 2016 **Process: 7708** Acorn 0014904 17 Jun 2016 **Process: 7798** Orders And Items Shipped Per Month 10 May 2017 **Process: 6961** Responsibility Allocation : VIAMED Stock Meeting Purchase Order Requirements 09 Mar 2016 **Process: 7683** Check Stock For Proforma 18 Apr 2016 **Process: 6968** Responsibility Allocation : VIAMED Stock Meeting Repairs Review - General 09 Mar 2016 **Process: 6949** Responsibility Allocation : VIAMED Stock Meeting QA Processing 09 Mar 2016 **Process: 6948** Responsibility Allocation : VIAMED Stock Meeting Stock Processing 09 Mar 2016 **Process: 6947** Responsibility Allocation : VIAMED Stock Meeting Stock Queries 09 Mar 2016 **Process: 7830** Review Q.A. Failures Report 18 Sep 2017 **Process: 7864** ESD Work Stations 07 Oct 2017 **Process: 7873** On Site Environment Review 18 Oct 2017 **Process: 7866** Oxygen Cylinder Check 13 Oct 2017
ID17284	**Audit 05 Purchasing suppliers** **Process: 7707** Send Purchase Orders To Suppliers 13 Jun 2016 **Process: 6972** UPS Shipping Fuel Surcharge 09 Mar 2016 **Process: 7717** Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 **Process: 5850** Purchase Order Log 17 Feb 2016 **Process: 7751** VST Purchase Order Log 02 Nov 2016 **Process: 7765** Audit 05 Purchasing Suppliers VST 08 Feb 2017 **Process: 7794** V1000 Commissions Review 30 Mar 2017 **Process: 7745** UPS Invoices Viamed 06 Oct 2016 **Process: 7746** UPS Invoices VST 06 Oct 2016 **Process: 7747** UPS Invoices Vandagraph 06 Oct 2016 **Process: 7790** Humanmed Invoice them For Previous Month 10 Mar 2017 **Process: 28** Supplier Review 16 Feb 2016 **Process: 6960** Purchase Back Orders Review 09 Mar 2016 **Process: 5855** Purchase Order Requirements Teledyne 17 Feb 2016

	Process: 5866 UPS Shipping Fuel Surcharge 17 Feb 2016 **Process: 5868** Return Goods To Suppliers 17 Feb 2016 **Process: 6829** Supplier Review - Outstanding orders 09 Mar 2016 **Process: 6832** Supplier Review Future orders 09 Mar 2016 **Process: 6848** Returns Stock Report 09 Mar 2016 **Process: 6952** Responsibility Allocation : Lost in Shipping Claims 09 Mar 2016 **Process: 6971** Responsibility Allocation : Freight Courier Cost Request 09 Mar 2016 **Process: 7679** Check Stock Requirements Supplier Teledyne 18 Apr 2016 **Process: 7680** Check Stock Requirements Supplier Envitec 18 Apr 2016 **Process: 7681** Check Stock Requirements Supplier Posey 18 Apr 2016 **Process: 7682** Check Stock Requirements Supplier Bluepoint 18 Apr 2016 **Process: 7784** Check Returns Supplier Envitec 15 Feb 2017 **Process: 7785** Check Returns Supplier Teledyne 15 Feb 2017 **Process: 7786** Check Returns Supplier Maxtec 15 Feb 2017 **Process: 7787** Check Returns All Supplier 15 Feb 2017 **Process: 34** Responsibility Allocation : Insurance Is Upto Date 16 Feb 2016 **Process: 7683** Check Stock For Proforma 18 Apr 2016
ID15552	**Audit 03 Design Control** **Process: 7716** Audit 03 Design Control Viamed 24 Aug 2016 **Process: 42** Responsibility Allocation : Design Documentation 16 Feb 2016 **Process: 7764** Audit 03 Design Control VST 08 Feb 2017 **Process: 7043** Responsibility Allocation : Planning of product realization 09 Mar 2016 **Process: 7045** Design and Development 09 Mar 2016 **Process: 7047** Responsibility Allocation : Production and service provision 09 Mar 2016 **Process: 6942** Responsibility Allocation : Co ordination of Implementation 09 Mar 2016 **Process: 7173** Responsibility Allocation : Material Generation 09 Mar 2016 **Process: 5887** Review ISO/EN Documents 24 Feb 2016
ID22427	**VOP 27 Software Validation** **Process: 7851** Software Validation Scan Un-QA Product To Order 01 Oct 2017 **Process: 7852** Software Validation Expired Stock 01 Oct 2017 **Process: 7853** Software Validation Non Sell Able Shelf 01 Oct 2017 **Process: 7854** Software Validation In Production List 01 Oct 2017 **Process: 7855** Software Validation - Production Lists 01 Oct 2017 **Process: 7856** Software Validation Unchecked Orders 01 Oct 2017 **Process: 7857** Software Validation Stock Tracking Check 01 Oct 2017 **Process: 7858** Software Validation Attempt To QA Some Stock 01 Oct 2017 **Process: 7861** Software Validation Of Training Documents Forced Reading 03 Oct 2017 **Process: 7850** Software Validation Scan In Correct Product 01 Oct 2017 **Process: 7865** Software Validation Conflicting Audits 07 Oct 2017 **Process: 7870** Software Validation Non Conformance Product Risk Feedback Loop 15 Oct 2017
ID22684	**VM3COP00.00 Viamed Quality Statement policy and objectives** **Process: 23** Company Objectives 16 Feb 2016 **Process: 22** Company Policys 16 Feb 2016 **Process: 7828** Review The Quality Policy Viamed 16 Sep 2017 **Process: 7833** Importance Of Effective Quality Management 20 Sep 2017
ID22062	**VM3COP00.00 VST Quality Statement policy and objectives** **Process: 23** Company Objectives 16 Feb 2016 **Process: 7827** Review The Quality Policy VST 16 Sep 2017 **Process: 7833** Importance Of Effective Quality Management 20 Sep 2017
ID22838	**VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** **Process: 7871** Review Exclusion From Viamed 13485:2016 And VST 9001:2015 15 Oct 2017
ID9182	**VOP 17 Design Research and Development** **Process: 42** Responsibility Allocation : Design Documentation 16 Feb 2016 **Process: 43** Product Post Market Survelance 16 Feb 2016

	Process: 6975 Responsibility Allocation : Projects 09 Mar 2016 **Process: 7045** Design and Development 09 Mar 2016
ID20567	**Audit 23 Analysis of Data** **Process: 7733** Audit 23 Analysis Of Data Viamed 24 Aug 2016 **Process: 7781** Audit 23 Analysis Of Data VST 08 Feb 2017
ID6275	**VOP 10 VM3COP13.1 Corrective Actions** **Process: 7199** Non Conformities Review 09 Mar 2016 **Process: 7069** Responsibility Allocation : Corrective Actions 09 Mar 2016 **Process: 7849** Review Product Failures New Codes 28 Sep 2017 **Process: 7874** Review For Latest Version Med Dev 2.12. 18 Oct 2017
ID17316	**Audit 07 Handling and Storage** **Process: 6973** Responsibility Allocation : Stock Transfers. (QC19) 09 Mar 2016 **Process: 7719** Audit 07 Handling And Storage Viamed 24 Aug 2016 **Process: 7767** Audit 07 Handling And Storage VST 08 Feb 2017 **Process: 5858** Opera Stock Adjustments 17 Feb 2016 **Process: 5935** Stock Allocations 05 Mar 2016 **Process: 6840** Minimum Stock Report 09 Mar 2016 **Process: 6850** Current Stock Levels 09 Mar 2016 **Process: 6945** Missing Stock or Adjustments 09 Mar 2016 **Process: 7046** Stock Purchasing 09 Mar 2016 **Process: 7051** Responsibility Allocation : Control of nonconforming product 09 Mar 2016 **Process: 7673** Check Expiry Dated Stock 09 Mar 2016 **Process: 7688** Move Stock From QA Shelf To Stock Shelf Friday 21 Apr 2016 **Process: 7689** Move Stock From QA Shelf To Stock Shelf Monday 21 Apr 2016 **Process: 7694** Move Stock From QA Shelf To Stock Shelf Tuesday 28 Apr 2016 **Process: 7695** Top Up Quick Shipping Shelves 28 Apr 2016
ID13379	**VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks** **Process: 39** Enviromental Policy Document Review 16 Feb 2016 **Process: 7741** Review Ethical Policy 14 Sep 2016 **Process: 6839** Personnel Holidays and Time Adjustments 09 Mar 2016 **Process: 5881** Training Records Review 18 Feb 2016 **Process: 5904** Responsibility Allocation : Taking On New Staff 02 Mar 2016 **Process: 6837** Personnel Requirements and Training 09 Mar 2016 **Process: 6877** Responsibility Allocation : Alarm Key Holders 09 Mar 2016 **Process: 6906** Responsibility Allocation : Time Working Away 09 Mar 2016 **Process: 6928** Responsibility Allocation : Staff 09 Mar 2016 **Process: 7074** Training 09 Mar 2016 **Process: 7042** Responsibility Allocation : Work Environment 09 Mar 2016 **Process: 5934** Responsibility Allocation : Staff Training 05 Mar 2016 **Process: 5874** Childcare Vouchers Edenred 17 Feb 2016 **Process: 7753** Management Meeting 22 Nov 2016 **Process: 34** Responsibility Allocation : Insurance Is Upto Date 16 Feb 2016 **Process: 5869** Responsibility Allocation : Legal Company Car Registration 17 Feb 2016 **Process: 6841** Responsibility Allocation : Grants 09 Mar 2016 **Process: 6843** Future Reviews - Waste 09 Mar 2016 **Process: 6861** Management Meeting Review Weekly Meeting 09 Mar 2016 **Process: 30** Responsibility Allocation : MHRA Licences And Notifications 16 Feb 2016 **Process: 31** Responsibility Allocation : Notified Body Notifications 16 Feb 2016 **Process: 32** MDALL Listings 16 Feb 2016 **Process: 7033** Responsibility Allocation : Management commitment to ISO 09 Mar 2016 **Process: 7037** Responsibility Allocation : Responsibility, authority and communication 09 Mar 2016 **Process: 7057** Responsibility Allocation : Complaints and Vigilance Notifications 09 Mar 2016 **Process: 7713** Review Roles And Responsibilitys 17 Aug 2016 **Process: 7837** Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017

	Process: 29 Responsibility Allocation : CMDCAS Updates And Licences 16 Feb 2016 **Process: 7848** Review ISO Scopes 27 Sep 2017
ID8672	**VOP 18 Maintenance Building, Fabric and Infrastructure** **Process: 5856** Cleaning The Kitchen 17 Feb 2016 **Process: 5853** Vacuuming Of The Office, Hall And Meeting Room 17 Feb 2016 **Process: 5900** Cleaning Of Office Windows 25 Feb 2016 **Process: 5878** Empty Office Bins 18 Feb 2016 **Process: 5912** Responsibility Allocation : Main Recycle Bins 03 Mar 2016 **Process: 5906** Empty Paper Bins 03 Mar 2016 **Process: 7805** Empty Kitchen Bins 22 May 2017 **Process: 5909** Empty Warehouse Bins 03 Mar 2016 **Process: 7706** Update Virus Software And Scan For Viruses 10 Jun 2016 **Process: 7802** Clean Kitchen Sides 22 May 2017 **Process: 7803** Dishwashing 22 May 2017 **Process: 7804** Sweep Kitchen Floor 22 May 2017 **Process: 7806** Watering Plants 22 May 2017 **Process: 7807** **Process: 54** Responsibility Allocation : Gents Toilets 17 Feb 2016 **Process: 5907** Hoover Warehouse 03 Mar 2016 **Process: 5908** Sweep Warehouse 03 Mar 2016 **Process: 5910** Clean Duckets 03 Mar 2016 **Process: 5911** Responsibility Allocation : Clear Cardboard 03 Mar 2016 **Process: 7698** Clean Toilets 17 May 2016 **Process: 7131** Responsibility Allocation : Intrastats Opera 09 Mar 2016 **Process: 7133** Responsibility Allocation : Intrastats Contact Manager 09 Mar 2016 **Process: 7132** Responsibility Allocation : Intrastats Goldmine 09 Mar 2016
ID21800	**VM3COP19 Health and Safety** **Process: 6855** Risk Assessment HSE 09 Mar 2016
ID22429	**Viamed Top Level Quality Objectives** **Process: 23** Company Objectives 16 Feb 2016
ID22950	**VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** **Process: 5** Processing Of Sales Orders 16 Feb 2016 **Process: 10** Distribution Of Emails 16 Feb 2016 **Process: 36** Emailing Of Invoices 16 Feb 2016 **Process: 5892** Checking EBay And Amazon For Orders And Messages 25 Feb 2016 **Process: 5894** Responsibility Allocation : Checking Of Active List 25 Feb 2016 **Process: 7** Checking Of Sales Orders 16 Feb 2016 **Process: 5943** Check Cardea And Multiquote 08 Mar 2016 **Process: 5891** Processing Of Repair Quotes And Orders 25 Feb 2016 **Process: 11** Distribution Of Mail 16 Feb 2016 **Process: 2** Answering Telephones 16 Feb 2016 **Process: 37** West Yorkshire Ambulance Stock 16 Feb 2016 **Process: 5948** Adding New Accounts To Opera 08 Mar 2016 **Process: 5949** Filling Credit Card Slips 08 Mar 2016 **Process: 6** Updating Contact Management System 16 Feb 2016 **Process: 5895** Responsibility Allocation : Completing Office Job List 25 Feb 2016 **Process: 5901** Link Call Log Contacts To The CRM 02 Mar 2016 **Process: 5875** Check Paypal For Orders 17 Feb 2016 **Process: 5944** Chasing Lost Customers 08 Mar 2016 **Process: 3** Responsibility Allocation : Meeting And Greeting Visitors To The Company 16 Feb 2016 **Process: 4** Responsibility Allocation : Assisting With Refreshments For Visitors 16 Feb 2016 **Process: 7676** PDFing Of Invoices 17 Mar 2016 **Process: 9** Distribution Of Faxes 16 Feb 2016 **Process: 7696** Send VIAMED Delivery Notifications 28 Apr 2016 **Process: 5857** Customer Service Logs 17 Feb 2016

	Process: 5893 Answering Website Questions 25 Feb 2016 **Process: 7678** Check Catalog 360 Circle For Quotes And Orders 08 Apr 2016 **Process: 15** Filing and Archiving 16 Feb 2016 **Process: 5899** Proforma And Quote Chasing 25 Feb 2016 **Process: 7710** Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016 **Process: 7707** Send Purchase Orders To Suppliers 13 Jun 2016 **Process: 14** Fax Paper 16 Feb 2016 **Process: 5882** Responsibility Allocation : Send Post To Humanmed 24 Feb 2016 **Process: 7734** Humanmed Order Processing 25 Aug 2016 **Process: 5850** Purchase Order Log 17 Feb 2016 **Process: 7693** Collect Repair Filing From Warehouse 22 Apr 2016 **Process: 7677** Follow Up SOR And Samples 29 Mar 2016 **Process: 5897** Responsibility Allocation : Franking Mail 25 Feb 2016 **Process: 21** Office Sales Projects 16 Feb 2016 **Process: 7709** Humanmed Invoicing 28 Jun 2016 **Process: 8** Order Acknowledgment And Status Liaison With Customers Regarding 16 Feb 2016 **Process: 12** Sales And Technical Information Processing 16 Feb 2016 **Process: 16** Responsibility Allocation : Photocopying 16 Feb 2016 **Process: 17** Preparation Of Catalogues 16 Feb 2016 **Process: 20** Processing Of Mail Shots 16 Feb 2016 **Process: 5896** Responsibility Allocation : Ensuring ORD`s Are Taken To Goods Out And Invoices Are Retrieved 25 Feb 2016 **Process: 5913** Check For Humanmed Orders In Logistics Mailbox 03 Mar 2016 **Process: 5947** Responsibility Allocation : Search For Distributors 08 Mar 2016 **Process: 6958** Responsibility Allocation : Shipped Order Queries 09 Mar 2016 **Process: 7686** Thorough Checking Of Awaiting Action Tray 21 Apr 2016 **Process: 7699** Shred Sensitive Paperwork In JL Office 19 May 2016 **Process: 7705** Checking For Uploaded Files 08 Jun 2016 **Process: 7712** Review Inward Payments 01 Jul 2016 **Process: 7735** Ensure SOR`s Are Followed Up 01 Sep 2016 **Process: 7751** VST Purchase Order Log 02 Nov 2016 **Process: 7758** Check For GHX Orders 17 Jan 2017 **Process: 7760** Send Service Offers 31 Jan 2017 **Process: 7761** Send VST Delivery Notifications 01 Feb 2017 **Process: 7783** PDF VST Invoices And Purchase Orders 10 Feb 2017 **Process: 7792** Shipped Order Success Report 13 Mar 2017 **Process: 7795** Answering UK Web Questions 27 Apr 2017 **Process: 7822** Review Oxylink Stock 26 Jul 2017 **Process: 5876** E.Commerce Cardea And Multiquote 17 Feb 2016 **Process: 5873** Distributor Contract Reviews 17 Feb 2016 **Process: 5885** Responsibility Allocation : Monthly Reports 24 Feb 2016 **Process: 6938** Customer Database Updates 09 Mar 2016 **Process: 6940** Responsibility Allocation : Customer Ongoing task List 09 Mar 2016 **Process: 6956** Responsibility Allocation : Sales Order Issues 09 Mar 2016 **Process: 5866** UPS Shipping Fuel Surcharge 17 Feb 2016 **Process: 6952** Responsibility Allocation : Lost in Shipping Claims 09 Mar 2016 **Process: 6971** Responsibility Allocation : Freight Courier Cost Request 09 Mar 2016 **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office 22 Apr 2016 **Process: 7796** Review Franking Label Errors 08 May 2017 **Process: 6916** Responsibility Allocation : Service exisiting 09 Mar 2016 **Process: 6917** Responsibility Allocation : Service extension 09 Mar 2016 **Process: 7863** Maintain Repair Codes List 05 Oct 2017
ID18641	**VM3COP20.01 Post In Distributing the Post** **Process: 11** Distribution Of Mail 16 Feb 2016 **Process: 5882** Responsibility Allocation : Send Post To Humanmed 24 Feb 2016
ID17280	**Audit 02 Contract Review and Sales Order Processing**

Process: 5 Processing Of Sales Orders 16 Feb 2016
Process: 36 Emailing Of Invoices 16 Feb 2016
Process: 5892 Checking EBay And Amazon For Orders And Messages 25 Feb 2016
Process: 5894 Responsibility Allocation : Checking Of Active List 25 Feb 2016
Process: 7 Checking Of Sales Orders 16 Feb 2016
Process: 5943 Check Cardea And Multiquote 08 Mar 2016
Process: 5891 Processing Of Repair Quotes And Orders 25 Feb 2016
Process: 2 Answering Telephones 16 Feb 2016
Process: 37 West Yorkshire Ambulance Stock 16 Feb 2016
Process: 5945 Responsibility Allocation : Sending Samples 08 Mar 2016
Process: 5946 Sending Sale Or Returns 08 Mar 2016
Process: 5948 Adding New Accounts To Opera 08 Mar 2016
Process: 5949 Filling Credit Card Slips 08 Mar 2016
Process: 5895 Responsibility Allocation : Completing Office Job List 25 Feb 2016
Process: 5875 Check Paypal For Orders 17 Feb 2016
Process: 7675 Responsibility Allocation : Ordering Demo Stock For Humanmed Reps 11 Mar 2016
Process: 5944 Chasing Lost Customers 08 Mar 2016
Process: 3 Responsibility Allocation : Meeting And Greeting Visitors To The Company 16 Feb 2016
Process: 4 Responsibility Allocation : Assisting With Refreshments For Visitors 16 Feb 2016
Process: 7676 PDFing Of Invoices 17 Mar 2016
Process: 7696 Send VIAMED Delivery Notifications 28 Apr 2016
Process: 5893 Answering Website Questions 25 Feb 2016
Process: 7678 Check Catalog 360 Circle For Quotes And Orders 08 Apr 2016
Process: 5899 Proforma And Quote Chasing 25 Feb 2016
Process: 7710 Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016
Process: 14 Fax Paper 16 Feb 2016
Process: 5882 Responsibility Allocation : Send Post To Humanmed 24 Feb 2016
Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016
Process: 7734 Humanmed Order Processing 25 Aug 2016
Process: 7677 Follow Up SOR And Samples 29 Mar 2016
Process: 5897 Responsibility Allocation : Franking Mail 25 Feb 2016
Process: 7709 Humanmed Invoicing 28 Jun 2016
Process: 6954 Back Orders Review - By Customer 09 Mar 2016
Process: 8 Order Acknowledgment And Status Liaison With Customers Regarding 16 Feb 2016
Process: 5896 Responsibility Allocation : Ensuring ORD`s Are Taken To Goods Out And Invoices Are Retrieved 25 Feb 2016
Process: 5913 Check For Humanmed Orders In Logistics Mailbox 03 Mar 2016
Process: 5947 Responsibility Allocation : Search For Distributors 08 Mar 2016
Process: 6958 Responsibility Allocation : Shipped Order Queries 09 Mar 2016
Process: 7686 Thorough Checking Of Awaiting Action Tray 21 Apr 2016
Process: 7712 Review Inward Payments 01 Jul 2016
Process: 7735 Ensure SOR`s Are Followed Up 01 Sep 2016
Process: 7758 Check For GHX Orders 17 Jan 2017
Process: 7761 Send VST Delivery Notifications 01 Feb 2017
Process: 7783 PDF VST Invoices And Purchase Orders 10 Feb 2017
Process: 7795 Answering UK Web Questions 27 Apr 2017
Process: 7822 Review Oxylink Stock 26 Jul 2017
Process: 7791 Price List Check 10 Mar 2017
Process: 7763 Audit 02 Contract Review VST 08 Feb 2017
Process: 7808 Ensure All Invoice Correctly Tagged 02 Jun 2017
Process: 5872 Check Sale Or Returns Export 17 Feb 2016
Process: 5871 Check Sale Or Returns 17 Feb 2016
Process: 5876 E.Commerce Cardea And Multiquote 17 Feb 2016
Process: 7782 Remove Started But Not Used Order Numbers 08 Feb 2017
Process: 6956 Responsibility Allocation : Sales Order Issues 09 Mar 2016
Process: 6921 Customer pricing agreements 09 Mar 2016

	Process: 6922 Special Price Quotes to Customers 09 Mar 2016 **Process: 6959** Sales Forward Orders Review 09 Mar 2016 **Process: 7801** VST Price Review 17 May 2017 **Process: 5905** Responsibility Allocation : Price Checking 02 Mar 2016 **Process: 6950** Opera Partnumber Prices Updates 09 Mar 2016 **Process: 7697** Yearly Pricing Review 09 May 2016 **Process: 7670** Humanmed general Issues 09 Mar 2016
ID17419	**VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7671** Humanmed Non Conformances 09 Mar 2016 **Process: 6931** Customer Complaints 09 Mar 2016 **Process: 7839** Review VIAMED Feedback - Customer Complaints 23 Sep 2017 **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 **Process: 7840** Review VST Feedback - Customer Feedback Negative 23 Sep 2017 **Process: 7841** Review VST Feedback - Customer Complaints 23 Sep 2017 **Process: 7842** Review VIAMED Product Feedback Negative 23 Sep 2017 **Process: 7843** Review VST Product Feedback Negative 23 Sep 2017 **Process: 7174** Responsibility Allocation : VIAMED Feedback Product Feedback Positive 09 Mar 2016 **Process: 7175** Responsibility Allocation : VIAMED Feedback Product Feedback Negative 09 Mar 2016 **Process: 7179** Responsibility Allocation : VIAMED Feedback Product Innovation 09 Mar 2016
ID22086	**Audit 04 Accounts and Finance** **Process: 7702** Responsibility Allocation : Vandagraph Pay Pay Issue Refund 23 May 2016 **Process: 7703** Vandagraph Pay Pay Retrieve Funds 23 May 2016 **Process: 5915** Opera Sales Ledger Close 05 Mar 2016 **Process: 7740** Weights Per Region Needed To Submit EC Sales List 13 Sep 2016 **Process: 5929** HMRC Intrastats Sales Data 05 Mar 2016 **Process: 7799** Opera Purchase Ledger Close 11 May 2017 **Process: 7800** Opera Nominal Ledger Close 11 May 2017 **Process: 5937** Review the Delivered Not Invoiced Reports 05 Mar 2016 **Process: 5865** Vandagraph Loan 17 Feb 2016 **Process: 5867** Accounts On Stop 17 Feb 2016 **Process: 5874** Childcare Vouchers Edenred 17 Feb 2016 **Process: 5914** End Of Year Reports For Accountants 04 Mar 2016 **Process: 5916** Bank Details Opera reports entered Intrastats 05 Mar 2016 **Process: 5917** Fill in Cashbook / Bank Rec for previous Month 05 Mar 2016 **Process: 5918** Journals for the End of Month accounts 05 Mar 2016 **Process: 5920** Responsibility Allocation : Cheques To Bank - Fill in Paying in Book 05 Mar 2016 **Process: 5922** Credit Cards Expenses Calculations 05 Mar 2016 **Process: 5923** Credits processed 05 Mar 2016 **Process: 5924** Export Cheques sent by Currency Lodgement 05 Mar 2016 **Process: 5925** Customs Clearance 05 Mar 2016 **Process: 5926** Responsibility Allocation : Petty Cash Expenses receipts and cash 05 Mar 2016 **Process: 5927** Responsibility Allocation : Accounts Filing 05 Mar 2016 **Process: 5928** Responsibility Allocation : xx remove Filing Cabinets 05 Mar 2016 **Process: 5930** VAT Return 05 Mar 2016 **Process: 5931** Purchase Invoices in to Opera 05 Mar 2016 **Process: 5932** Remit Processing and entry into Opera 05 Mar 2016 **Process: 5933** Responsibility Allocation : Sales Accounts Reminders 05 Mar 2016 **Process: 5942** Chase the Debtors viamed 08 Mar 2016 **Process: 6819** Supplier Payments and Invoice processing 09 Mar 2016 **Process: 6822** Responsibility Allocation : xx remove Banking Issues 09 Mar 2016 **Process: 6876** Issues for Accountants - P11D Form re Benefits to Revenue and Customs 09 Mar 2016

	Process: 6946 Accounts Debtors Review - Export 09 Mar 2016 **Process: 6951** Accounts Debtors Review - UK 09 Mar 2016 **Process: 7192** Responsibility Allocation : xx remove Overdraft 09 Mar 2016 **Process: 7084** Responsibility Allocation : Accounts Issues 09 Mar 2016 **Process: 7195** Responsibility Allocation : Loans between companies 09 Mar 2016 **Process: 7788** Petty Cash Reconciliation 02 Mar 2017 **Process: 7789** Withdraw Funds From Paypal 02 Mar 2017 **Process: 7817** Issues For Accountants - Check suggested invoice report in operas 13 Jun 2017 **Process: 7818** Issues For Accountants - Check Purchasing Journals to see if VAT handled correctly Previous Month 13 Jun 2017 **Process: 7819** Issues For Accountant - Check Contra account 8000 and clear it 13 Jun 2017 **Process: 7824** Chase The Debtors VST 27 Aug 2017 **Process: 7708** Acorn 0014904 17 Jun 2016 **Process: 5869** Responsibility Allocation : Legal Company Car Registration 17 Feb 2016 **Process: 7831** Intrastats Debtors And Creditor Figures 18 Sep 2017
ID22080	**Audit 16 Sales and Marketing** **Process: 21** Office Sales Projects 16 Feb 2016 **Process: 40** Responsibility Allocation : Calender 16 Feb 2016 **Process: 5870** Book Arab Health 17 Feb 2016 **Process: 19** Maintaining Leaflet Stocks 16 Feb 2016 **Process: 20** Processing Of Mail Shots 16 Feb 2016 **Process: 5873** Distributor Contract Reviews 17 Feb 2016 **Process: 5885** Responsibility Allocation : Monthly Reports 24 Feb 2016 **Process: 5883** Responsibility Allocation : Monthly Sales Report 24 Feb 2016 **Process: 5884** Responsibility Allocation : Monthly Report 24 Feb 2016 **Process: 5886** Responsibility Allocation : Monthly Report 24 Feb 2016
ID9033	**Audit 08 Training, Competence and Human Resources** **Process: 7720** Audit 08 Training Viamed 24 Aug 2016 **Process: 6839** Personnel Holidays and Time Adjustments 09 Mar 2016 **Process: 5881** Training Records Review 18 Feb 2016 **Process: 5904** Responsibility Allocation : Taking On New Staff 02 Mar 2016 **Process: 5936** Wages Calculations 05 Mar 2016 **Process: 6837** Personnel Requirements and Training 09 Mar 2016 **Process: 6851** Review Accident Book 09 Mar 2016 **Process: 6877** Responsibility Allocation : Alarm Key Holders 09 Mar 2016 **Process: 6906** Responsibility Allocation : Time Working Away 09 Mar 2016 **Process: 6928** Responsibility Allocation : Staff 09 Mar 2016 **Process: 7074** Training 09 Mar 2016 **Process: 7759** Health Declaration Sheet 23 Jan 2017 **Process: 7768** Audit 08 Training VST 08 Feb 2017 **Process: 5934** Responsibility Allocation : Staff Training 05 Mar 2016 **Process: 7070** Management Review 09 Mar 2016 **Process: 7713** Review Roles And Responsibilitys 17 Aug 2016
ID21806	**Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** **Process: 5941** Responsibility Allocation : Replace Main Server 07 Mar 2016 **Process: 45** Responsibility Allocation : Main Server Status 16 Feb 2016 **Process: 46** Responsibility Allocation : Backup Server Status 16 Feb 2016 **Process: 7704** Responsibility Allocation : Computer Failure Diagnostics 24 May 2016 **Process: 5856** Cleaning The Kitchen 17 Feb 2016 **Process: 7729** Audit 19 Health And Saftey Viamed 24 Aug 2016 **Process: 5853** Vacuuming Of The Office, Hall And Meeting Room 17 Feb 2016 **Process: 5900** Cleaning Of Office Windows 25 Feb 2016 **Process: 39** Enviromental Policy Document Review 16 Feb 2016 **Process: 7741** Review Ethical Policy 14 Sep 2016 **Process: 5878** Empty Office Bins 18 Feb 2016 **Process: 5912** Responsibility Allocation : Main Recycle Bins 03 Mar 2016 **Process: 7821** Controlled Waste Description And Transfer 15 Jun 2017

	Process: 7820 North Yorkshire Council Waste Tranfer 15 Jun 2017 **Process: 5906** Empty Paper Bins 03 Mar 2016 **Process: 7805** Empty Kitchen Bins 22 May 2017 **Process: 5909** Empty Warehouse Bins 03 Mar 2016 **Process: 7042** Responsibility Allocation : Work Environment 09 Mar 2016 **Process: 7706** Update Virus Software And Scan For Viruses 10 Jun 2016 **Process: 7802** Clean Kitchen Sides 22 May 2017 **Process: 7803** Dishwashing 22 May 2017 **Process: 7804** Sweep Kitchen Floor 22 May 2017 **Process: 7806** Watering Plants 22 May 2017 **Process: 7807** **Process: 7777** Audit 19 Health And Saftey VST 08 Feb 2017 **Process: 54** Responsibility Allocation : Gents Toilets 17 Feb 2016 **Process: 5907** Hoover Warehouse 03 Mar 2016 **Process: 5908** Sweep Warehouse 03 Mar 2016 **Process: 5910** Clean Duckets 03 Mar 2016 **Process: 5911** Responsibility Allocation : Clear Cardboard 03 Mar 2016 **Process: 7687** Vandagraph Duckets 21 Apr 2016 **Process: 7698** Clean Toilets 17 May 2016 **Process: 6849** First Aid 09 Mar 2016 **Process: 6855** Risk Assessment HSE 09 Mar 2016 **Process: 6856** Fire Alarms 09 Mar 2016 **Process: 7092** P.A.T. Testing 09 Mar 2016 **Process: 56** Warehouse Outside Heating Guard 17 Feb 2016 **Process: 5919** Check Out Side Drain 05 Mar 2016 **Process: 5921** Clearing Water Downstairs 05 Mar 2016 **Process: 7120** General Maintenance Requirements 09 Mar 2016 **Process: 7742** Boiler Check 26 Sep 2016 **Process: 7756** Carbon Monoxide Alarm 05 Jan 2017 **Process: 48** Responsibility Allocation : Internet 16 Feb 2016 **Process: 49** Responsibility Allocation : Wifi 16 Feb 2016 **Process: 50** Responsibility Allocation : Guest Access Wifi 16 Feb 2016 **Process: 51** Responsibility Allocation : Printers 16 Feb 2016 **Process: 5903** Responsibility Allocation : Weather Station 02 Mar 2016 **Process: 7121** Responsibility Allocation : General Computer Maintenance 09 Mar 2016 **Process: 7178** Responsibility Allocation : Systems Innovation 09 Mar 2016 **Process: 6843** Future Reviews - Waste 09 Mar 2016 **Process: 7835** Electrics Need Checking 20 Sep 2017 **Process: 7836** Central Heating For Winter 20 Sep 2017 **Process: 7847** Health And Safety Review 26 Sep 2017 **Process: 7864** ESD Work Stations 07 Oct 2017 **Process: 7867** Bandsaw Checklist 13 Oct 2017 **Process: 7868** Pillar Drill Checklist 13 Oct 2017 **Process: 7869** Hand Drill Checklist 13 Oct 2017
ID13697	**VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 6931** Customer Complaints 09 Mar 2016
ID9037	**Audit 21 Audit of Audit** **Process: 7731** Audit 21 Audit Of Audit Viamed 24 Aug 2016 **Process: 7779** Audit 21 Audit Of Audit VST 08 Feb 2017 **Process: 38** Audits Up to Date and Confirm next years Audit schedule 16 Feb 2016 **Process: 7093** BSI Audits Calander 09 Mar 2016 **Process: 7670** Humanmed general Issues 09 Mar 2016
ID9386	**Audit 22 Post Market Survellance** **Process: 7732** Audit 22 Post Market Survellance Viamed 24 Aug 2016 **Process: 43** Product Post Market Survelance 16 Feb 2016 **Process: 7780** Audit 22 Post Market Survellance VST 08 Feb 2017

	Process: 7071 Post Market Surveillance 09 Mar 2016 **Process: 6889** Responsibility Allocation : Post Market Surveilance 09 Mar 2016 **Process: 7809** Pro-Active Marketing 06 Jun 2017 **Process: 7810** Research Activities 06 Jun 2017 **Process: 5863** Responsibility Allocation : Sales Meetings UK 17 Feb 2016 **Process: 5864** Responsibility Allocation : Sales Meeting EX 17 Feb 2016
ID9273	**Audit 14 Complaints and Corrective Actions** **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 **Process: 6828** Non Conformance Issues 09 Mar 2016 **Process: 7743** Customer Complaints Paper File 26 Sep 2016 **Process: 7774** Audit 14 Complaints And Corrective Actions VST 08 Feb 2017 **Process: 6865** Responsibility Allocation : Non Conformance Effectiveness 09 Mar 2016 **Process: 7199** Non Conformities Review 09 Mar 2016 **Process: 7671** Humanmed Non Conformances 09 Mar 2016 **Process: 6931** Customer Complaints 09 Mar 2016 **Process: 7839** Review VIAMED Feedback - Customer Complaints 23 Sep 2017 **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 **Process: 7840** Review VST Feedback - Customer Feedback Negative 23 Sep 2017 **Process: 7841** Review VST Feedback - Customer Complaints 23 Sep 2017 **Process: 7842** Review VIAMED Product Feedback Negative 23 Sep 2017 **Process: 7843** Review VST Product Feedback Negative 23 Sep 2017 **Process: 7849** Review Product Failures New Codes 28 Sep 2017
ID14696	**Process: 6972** UPS Shipping Fuel Surcharge 09 Mar 2016
ID17155	**VM3COP03.05 Procedures for customer returning goods on our UPS account number** **Process: 5879** Customer Returning Goods On Our UPS Account 18 Feb 2016
ID17395	**Audit 09 Goods Inward and Product Identity** **Process: 5938** Responsibility Allocation : Receive Goods 05 Mar 2016 **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 **Process: 7826** Goods In Processes 06 Sep 2017 **Process: 7792** Shipped Order Success Report 13 Mar 2017 **Process: 7769** Audit 09 Goods Inward And Product Identity VST 08 Feb 2017 **Process: 6969** Responsibility Allocation : VIAMED Stock Meeting `Goods In` Review 09 Mar 2016 **Process: 57** Temporary Stock Notices 17 Feb 2016 **Process: 5854** Stock FAQ Admin List 17 Feb 2016 **Process: 7181** Responsibility Allocation : Product Catagories 09 Mar 2016 **Process: 6894** Product Cross References 09 Mar 2016 **Process: 6838** Opera Negative Stock 09 Mar 2016 **Process: 7830** Review Q.A. Failures Report 18 Sep 2017 **Process: 7859** Check POR Files For Items Delivered But Not Removed From File 02 Oct 2017
ID6268	**VOP 06 Measurement Control Viamed, Calibration, QA Stock** **Process: 7091** Calibration Index 09 Mar 2016
ID17384	**Audit 15 Production** **Process: 7727** Audit 15 Production Viamed 24 Aug 2016 **Process: 7736** Production Start Job List 03 Sep 2016 **Process: 7737** Production In Production List 03 Sep 2016 **Process: 7738** Production Statistics 03 Sep 2016 **Process: 7775** Audit 15 Production VST 08 Feb 2017 **Process: 6845** Responsibility Allocation : Quarantine Production 09 Mar 2016 **Process: 6955** Production Requirements 09 Mar 2016 **Process: 7169** Responsibility Allocation : Production 09 Mar 2016 **Process: 7170** Responsibility Allocation : Production Production Schedule 09 Mar 2016 **Process: 7171** Responsibility Allocation : Production Production Problems 09 Mar 2016 **Process: 7072** Responsibility Allocation : Manufacturing Processes 09 Mar 2016

ID17472	**Viamed Environment Policy Inc WEEE** **Process: 39** Enviromental Policy Document Review 16 Feb 2016
ID7664	**Audit 01 Picking packing** **Process: 7714** Audit 01 Picking Packing Viamed 24 Aug 2016 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017 **Process: 5859** Review Un-shipped Parcels 17 Feb 2016 **Process: 6970** Goods Out Review 09 Mar 2016 **Process: 7691** Ship Sale Or Returns 21 Apr 2016 **Process: 7762** Audit 01 Picking Packing VST 08 Feb 2017 **Process: 7796** Review Franking Label Errors 08 May 2017 **Process: 7797** Check Order Are Being Picked In Priority Order 10 May 2017 **Process: 7798** Orders And Items Shipped Per Month 10 May 2017 **Process: 7860** Goods Out Picking 03 Oct 2017
ID22016	**VM3COP20.31 Export Order Processing** **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017
ID20049	**VM3COP03.01 Order Processing Priorities** **Process: 5** Processing Of Sales Orders 16 Feb 2016 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017
ID22527	**VM3COP20.30 UK Order Processing** **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017
ID22266	**VM3COP03.07 Humanmed Order Checking** **Process: 7** Checking Of Sales Orders 16 Feb 2016 **Process: 7734** Humanmed Order Processing 25 Aug 2016 **Process: 7709** Humanmed Invoicing 28 Jun 2016
ID22369	**VM3COP03.08 Humanmed Order Processing** **Process: 5** Processing Of Sales Orders 16 Feb 2016 **Process: 7734** Humanmed Order Processing 25 Aug 2016 **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017
ID8669	**VOP 14 Servicing Out of Building Servicing** **Process: 6916** Responsibility Allocation : Service exisiting 09 Mar 2016 **Process: 6917** Responsibility Allocation : Service extension 09 Mar 2016 **Process: 6920** Responsibility Allocation : VIAMED Sales And Marketing Price Lists UK 09 Mar 2016
ID17152	**VM3COP20.32 Order Checking** **Process: 7825** Responsibility Allocation : Order Picking 06 Sep 2017
ID17321	**Audit 11 Repairs, Servicing and Returns** **Process: 5898** Processing Depleted Sensors 25 Feb 2016 **Process: 5879** Customer Returning Goods On Our UPS Account 18 Feb 2016 **Process: 5857** Customer Service Logs 17 Feb 2016 **Process: 7724** Audit 11 Repairs And Service Viamed 24 Aug 2016 **Process: 7684** Repairs Ready For Quote 18 Apr 2016 **Process: 7685** Repairs Ready For Invoice 18 Apr 2016 **Process: 7690** Ship Repairs 21 Apr 2016 **Process: 7748** Check Repair Orders 10 Oct 2016 **Process: 7749** Check Repair Quotes 10 Oct 2016 **Process: 7752** SRS Folder 22 Nov 2016 **Process: 7760** Send Service Offers 31 Jan 2017 **Process: 7772** Audit 11 Repairs And Service VST 08 Feb 2017 **Process: 6847** Quarantine Repairs 09 Mar 2016 **Process: 6862** Current Repairs 09 Mar 2016 **Process: 7138** Non Conformance Issues Any New QC21 Forms 09 Mar 2016 **Process: 7674** Check Repairs Ready For Invoice List 10 Mar 2016 **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office 22 Apr 2016 **Process: 6916** Responsibility Allocation : Service exisiting 09 Mar 2016

	Process: 6917 Responsibility Allocation : Service extension 09 Mar 2016 **Process: 7823** Saftey Tester Data 02 Aug 2017
ID20584	**VM3COP27.31 Processing Proforma Invoices and Quotations** **Process: 7710** Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016
ID21314	**vop VM3COP20.11 Non-Conformances** **Process: 6828** Non Conformance Issues 09 Mar 2016
ID17299	**Audit 12 CE Files** **Process: 7725** Audit 12 CE Files Viamed 24 Aug 2016 **Process: 7773** Audit 12 CE Files VST 08 Feb 2017 **Process: 24** Compliance ISO Standards 16 Feb 2016 **Process: 7172** CE Technical Files 09 Mar 2016
ID20588	**VM3COP20.29 Checking the Purchase Order Log** **Process: 5850** Purchase Order Log 17 Feb 2016
ID17070	**VM3COP27.34 Sending Purchase Orders to Suppliers** **Process: 7707** Send Purchase Orders To Suppliers 13 Jun 2016
ID17282	**Audit 06 Calibration** **Process: 7718** Audit 06 Calibration Viamed 24 Aug 2016 **Process: 7766** Audit 06 Calibration VST 08 Feb 2017 **Process: 7048** Control of monitoring and measuring devices 09 Mar 2016 **Process: 7091** Calibration Index 09 Mar 2016
ID16987	**VM3COP20.27 Annual Services for Resuscitation Cabinets** **Process: 5857** Customer Service Logs 17 Feb 2016
ID8712	**VM3COP09 Repairs** **Process: 7684** Repairs Ready For Quote 18 Apr 2016 **Process: 7685** Repairs Ready For Invoice 18 Apr 2016 **Process: 7814** Responsibility Allocation : Viamed Repairs 06 Jun 2017
ID13703	**VM3COP20.03 Repair Procedures** **Process: 5891** Processing Of Repair Quotes And Orders 25 Feb 2016
ID17485	**VM3COP20.47 Collecting Repair Paperwork** **Process: 7693** Collect Repair Filing From Warehouse 22 Apr 2016
ID8798	**Audit 17 Internal Audits** **Process: 7728** Audit 17 Internal Audits Viamed 24 Aug 2016 **Process: 7776** Audit 17 Internal Audits VST 08 Feb 2017
ID6271	**VOP 09 Repairs External and Internal Repairs** **Process: 7684** Repairs Ready For Quote 18 Apr 2016 **Process: 7685** Repairs Ready For Invoice 18 Apr 2016 **Process: 7690** Ship Repairs 21 Apr 2016 **Process: 7752** SRS Folder 22 Nov 2016 **Process: 6847** Quarantine Repairs 09 Mar 2016 **Process: 6862** Current Repairs 09 Mar 2016 **Process: 7048** Control of monitoring and measuring devices 09 Mar 2016 **Process: 7674** Check Repairs Ready For Invoice List 10 Mar 2016 **Process: 7814** Responsibility Allocation : Viamed Repairs 06 Jun 2017 **Process: 7811** Responsibility Allocation : General Area 06 Jun 2017 **Process: 7812** Responsibility Allocation : Vandagraph Repairs 06 Jun 2017 **Process: 7813** Responsibility Allocation : VST Repairs 06 Jun 2017 **Process: 7815** Responsibility Allocation : Product Types To Relevant Person 06 Jun 2017
ID22946	**VOP 13 Process Monitoring, System Reviews, Audits, Management Review** **Process: 55** Business Continuity Plan 17 Feb 2016 **Process: 23** Company Objectives 16 Feb 2016 **Process: 27** Management Reviews And Quality Audits 16 Feb 2016 **Process: 7714** Audit 01 Picking Packing Viamed 24 Aug 2016 **Process: 7715** Audit 02 Contract Review Viamed 24 Aug 2016

Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016
Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
Process: 7718 Audit 06 Calibration Viamed 24 Aug 2016
Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016
Process: 7720 Audit 08 Training Viamed 24 Aug 2016
Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016
Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016
Process: 7723 Audit 10b Process Verification Viamed 21 Oct 2017
Process: 7724 Audit 11 Repairs And Service Viamed 24 Aug 2016
Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016
Process: 7726 Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016
Process: 7727 Audit 15 Production Viamed 24 Aug 2016
Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016
Process: 7729 Audit 19 Health And Saftey Viamed 24 Aug 2016
Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016
Process: 7731 Audit 21 Audit Of Audit Viamed 24 Aug 2016
Process: 7732 Audit 22 Post Market Surveillance Viamed 24 Aug 2016
Process: 7733 Audit 23 Analysis Of Data Viamed 24 Aug 2016
Process: 6828 Non Conformance Issues 09 Mar 2016
Process: 22 Company Policys 16 Feb 2016
Process: 7754 Ensure Procedures Are Up-to-date 24 Nov 2016
Process: 7762 Audit 01 Picking Packing VST 08 Feb 2017
Process: 7763 Audit 02 Contract Review VST 08 Feb 2017
Process: 7764 Audit 03 Design Control VST 08 Feb 2017
Process: 7765 Audit 05 Purchasing Suppliers VST 08 Feb 2017
Process: 7766 Audit 06 Calibration VST 08 Feb 2017
Process: 7767 Audit 07 Handling And Storage VST 08 Feb 2017
Process: 7768 Audit 08 Training VST 08 Feb 2017
Process: 7769 Audit 09 Goods Inward And Product Identity VST 08 Feb 2017
Process: 7770 Audit 10 Documentation Control VST 08 Feb 2017
Process: 7771 Audit 10b Process Verification VST 08 Feb 2017
Process: 7772 Audit 11 Repairs And Service VST 08 Feb 2017
Process: 7773 Audit 12 CE Files VST 08 Feb 2017
Process: 7774 Audit 14 Complaints And Corrective Actions VST 08 Feb 2017
Process: 7775 Audit 15 Production VST 08 Feb 2017
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Process: 7808 Ensure All Invoice Correctly Tagged 02 Jun 2017
Process: 6886 Responsibility Allocation : VIAMED Sales And Marketing Sales Viamed Medical Export 09 Mar 2016
Process: 6887 Responsibility Allocation : VIAMED Sales And Marketing Sales Viamed Automotive Export 09 Mar 2016
Process: 7204 Responsibility Allocation : VIAMED Board Directors Meeting Distributor Issues 09 Mar 2016
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Process: 7782 Remove Started But Not Used Order Numbers 08 Feb 2017
Process: 7090 Responsibility Allocation : Office Procedures 09 Mar 2016
Process: 7138 Non Conformance Issues Any New QC21 Forms 09 Mar 2016
Process: 57 Temporary Stock Notices 17 Feb 2016

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Process: 7043 Responsibility Allocation : Planning of product realization 09 Mar 2016
Process: 38 Audits Up to Date and Confirm next years Audit schedule 16 Feb 2016
Process: 5877 Responsibility Allocation : Review Company Data 17 Feb 2016
Process: 6904 Responsibility Allocation : Sales And Marketing Internal sales 09 Mar 2016
Process: 6944 Stock Meeting 09 Mar 2016
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Process: 26 Company Resources 16 Feb 2016
Process: 7070 Management Review 09 Mar 2016
Process: 5887 Review ISO/EN Documents 24 Feb 2016
Process: 5889 Responsibility Allocation : Audit And Task - Audit 24 Feb 2016
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Process: 7829 Complete Systems Review 17 Sep 2017
Process: 7670 Humanmed general Issues 09 Mar 2016
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Process: 6871 ISO14001 Environmental management systems 09 Mar 2016
Process: 7848 Review ISO Scopes 27 Sep 2017
Process: 7862 Review The Audit Calender Screen 04 Oct 2017