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

Version: 2017:23087

Listing of Current Sections

Section	Documents related	Processes related
4 Quality management system		
4.1 **Quality management system**	**ISO 13485:2016 Viamed Summary Listing** Revision Document id: 23085 Date Revision:21 Oct 2017 Reviewed:21 Oct 2017 **BS EN ISO 13485-2016** Revision Document id: 19400 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	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **BS5750 Viamed** Revision Document id: 21353 Date Revision:10 Aug 2017 Reviewed:10 Aug 2017 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Viamed ISO 13485:2016 Scope** Revision Document id: 22645 Date Revision:15 Oct 2017 Reviewed:15 Oct 2017	**Process: 7723** Audit 10b Process Verification Viamed

regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.		
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 id: 21556 Date Revision:22 Aug 2017 Reviewed:11 Oct 2017 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Chart 00 System Model** Revision Document id: 8674 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 01 System and Documentation** Revision Document id: 8675 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 02 Resource Management** Revision Document id: 8676 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 03 Customer Requirements** Revision Document id: 8677 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 04 Design and Development** Revision Document id: 8678 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 05 Product Realisation** Revision Document id: 8679 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 06 General Process Control** Revision Document id: 8680 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 07 Measurement and Analysis** Revision Document id: 8681 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 08 Correction and Prevention** Revision Document id: 8682 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 09 Management System** Revision Document id: 8683 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 10 Documentation** Revision Document id: 8684 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 11 Provision of Resources** Revision Document id: 8685 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 12 Infrastructure and Environment** Revision Document id: 8686 Date Revision:12 Oct	**Process: 7743** Customer Complaints Paper File **Process: 7723** Audit 10b Process Verification Viamed **Process: 7725** Audit 12 CE Files Viamed

2011 Reviewed:12 Oct 2011
Chart 13 Sales Orders
Revision Document id: 8687 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 15 Purchasing
Revision Document id: 8688 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 16 Internal Audits
Revision Document id: 8689 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 17 Design Repairs
Revision Document id: 8690 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 18 Calibration
Revision Document id: 8691 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 19 HSE Risk Assesments
Revision Document id: 8692 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 20 Production
Revision Document id: 8693 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 21 Repairs
Revision Document id: 8694 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 22 Stock Control
Revision Document id: 8695 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 23 Picking and Packing
Revision Document id: 8696 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 24 Goods Inwards
Revision Document id: 8697 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 25 Inspection and Test
Revision Document id: 8698 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 26 Data Analysis
Revision Document id: 8699 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 27 Customer Complaints Chart 27
Revision Document id: 8700 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 28 Quarantine and Hold
Revision Document id: 8701 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 29 Sales Acquisition
Revision Document id: 8702 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 30 System Design Plan
Revision Document id: 8703 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 31 Chart Interfaces
Revision Document id: 8704 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 32 Generic Sales Process
Revision Document id: 8705 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011

	Chart 33 Launch of a new product Revision Document id: 8706 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 34 Process Teams Org Chart** Revision Document id: 8707 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Audit 10b Process Verification** Revision Document id: 17350 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 id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **VM3COP27.01 Searching Intrastats Issues** Revision Document id: 6657 Date Revision:02 Nov 2009 Reviewed:02 Nov 2009 **VM3COP27.17 Complete Auto_calender Issues** Revision Document id: 16995 Date Revision:26 May 2016 Reviewed:26 May 2016 **Issues Overview** Revision Document id: 22272 Date Revision:27 Sep 2017 Reviewed:27 Sep 2017 **Intrastats overview** Revision Document id: 8925 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Employee Roles** Revision Document id: 20125 Date Revision:16 May 2017 Reviewed:16 May 2017 **Employee roles Example Process** Revision Document id: 20129 Date Revision:16 May 2017 Reviewed:16 May 2017 **VM3COP27.02 Collecting Emails and Distributing** Revision Document id: 20131 Date Revision:16 May 2017 Reviewed:16 May 2017 **Employee Roles Individual Processes** Revision Document id: 20127 Date Revision:16 May 2017 Reviewed:16 May 2017 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017	**Process: 27** Management Reviews And Quality Audits **Process: 7723** Audit 10b Process Verification Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 5889** Responsibility Allocation : Audit And Task - Audit **Process: 7714** Audit 01 Picking Packing Viamed **Process: 7715** Audit 02 Contract Review Viamed **Process: 7716** Audit 03 Design Control Viamed **Process: 7717** Audit 05 Purchasing Suppliers Viamed **Process: 7718** Audit 06 Calibration Viamed **Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7720** Audit 08 Training Viamed **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed **Process: 7722** Audit 10 Documentation Control Viamed **Process: 7724** Audit 11 Repairs And Service Viamed **Process: 7725** Audit 12 CE Files Viamed **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed **Process: 7727** Audit 15 Production Viamed **Process: 7728**

		Audit 17 Internal Audits Viamed **Process: 7729** Audit 19 Health And Saftey Viamed **Process: 7731** Audit 21 Audit Of Audit Viamed **Process: 7732** Audit 22 Post Market Survellance Viamed **Process: 7733** Audit 23 Analysis Of Data Viamed **Process: 26** Company Resources
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 id: 13387 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	**Process: 7725** Audit 12 CE Files Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed
4.1.5 For each quality management system process, the	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016	**Process: 7717** Audit 05 Purchasing Suppliers Viamed

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 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.	**Top Level Document: VOP 27 Software Validation** Revision Document id: 22427 Date Revision:04 Oct 2017 Reviewed:04 Oct 2017 **Intrastats Amendment Log** Revision Document id: 20136 Date Revision:16 May 2017 Reviewed:16 May 2017 **Validation of Intrastats** Revision Document id: 20140 Date Revision:16 May 2017 Reviewed:16 May 2017 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016	**Process: 7850** Software Validation Scan In Correct Product **Process: 7851** Software Validation Scan Un-QA Product To Order **Process: 7852** Software Validation Expired Stock **Process: 7853** Software Validation Non Sell Able Shelf **Process: 7854** Software Validation In Production List **Process: 7855** Software Validation - Production Lists **Process: 7856** Software Validation Unchecked Orders **Process: 7857**

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).		Software Validation Stock Tracking Check **Process: 7858** Software Validation Attempt To QA Some Stock **Process: 7861** Software Validation Of Training Documents Forced Reading **Process: 7865** Software Validation Conflicting Audits **Process: 7870** Software Validation Non Conformance Product Risk Feedback Loop
4.2 **Documentation requirements**	**Audit 10 Documentation Control** Revision Document id: 17324 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 id: 22684 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 id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Explaination Quality Objectives** Revision Document id: 18483 Date Revision:18 Jan 2017 Reviewed:18 Jan 2017 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document id: 22062 Date Revision:16 Sep 2017 Reviewed:16 Sep 2017 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **VM3COP00.01 Company objectives** Revision Document id: 22842 Date Revision:17 Oct 2017 Reviewed:17 Oct 2017	**Process: 23** Company Objectives **Process: 22** Company Policys **Process: 23** Company Objectives **Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7723** Audit 10b Process Verification Viamed **Process: 7834** Financial Review **Process: 7862** Review The Audit Calender Screen **Process: 27** Management Reviews And Quality Audits **Process: 5877** Responsibility Allocation : Review Company Data **Process: 6843** Future Reviews - Waste **Process: 6861** Management Meeting Review Weekly Meeting **Process: 7037** Responsibility Allocation : Responsibility, authority and communication **Process: 7057** Responsibility Allocation : Complaints and Vigilance Notifications **Process: 7070** Management Review

		Process: 7713 Review Roles And Responsibilitys **Process: 7830** Review Q.A. Failures Report **Process: 7837** Review External Parties Influencing The QMS VST / Viamed **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative **Process: 7839** Review VIAMED Feedback - Customer Complaints **Process: 7842** Review VIAMED Product Feedback Negative **Process: 7845** 7.1.4 Environment Of Operations **Process: 7848** Review ISO Scopes **Process: 7849** Review Product Failures New Codes **Process: 7120** General Maintenance Requirements **Process: 28** Supplier Review **Process: 5887** Review ISO/EN Documents **Process: 5889** Responsibility Allocation : Audit And Task - Audit **Process: 6828** Non Conformance Issues **Process: 6866** Internal Process Verification Complete Systems Review **Process: 7199** Non Conformities Review **Process: 7828** Review The Quality Policy Viamed **Process: 6821** Responsibility Allocation : VIAMED Management Meeting Supplier Review **Process: 7697** Yearly Pricing Review **Process: 57** Temporary Stock Notices
4.2.2 Quality manual The organization	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document id: 22838 Date Revision:16 Oct	**Process: 7723** Audit 10b Process Verification Viamed

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.	2017 Reviewed:16 Oct 2017 **Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document id: 21556 Date Revision:22 Aug 2017 Reviewed:11 Oct 2017 **Structure of the documentation used in the quality management system** Revision Document id: 18487 Date Revision:18 Jan 2017 Reviewed:18 Jan 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Viamed ISO 13485:2016 Scope** Revision Document id: 22645 Date Revision:15 Oct 2017 Reviewed:15 Oct 2017	**Process: 7730** Audit 20 Process Verification To Managment Viamed
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,	**Top Level Document: VOP 17 Design Research and Development** Revision Document id: 9182 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Route to Medical device files** Revision Document id: 18495 Date Revision:18 Jan 2017 Reviewed:18 Jan 2017 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016	**Process: 7716** Audit 03 Design Control Viamed **Process: 7723** Audit 10b Process Verification Viamed

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.		
4.2.4 Control of documents 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	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Explanation Control of documents** Revision Document id: 21322 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017 **VM3COP01 Document Updates / Amendment control** Revision Document id: 22201 Date Revision:23 Sep 2017 Reviewed:23 Sep 2017 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **VM3COP14 Documentation** Revision Document id: 9276 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7722** Audit 10 Documentation Control Viamed

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 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	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document id: 6275 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **VM3COP01 Document Updates / Amendment control** Revision Document id: 22201 Date Revision:23 Sep 2017 Reviewed:23 Sep 2017 **VM3COP14.01 Disposition of Documents / Records.** Revision Document id: 15464 Date Revision:14 Aug 2015 Reviewed:14 Aug 2015 **Guide to Intrastats** Revision Document id: 8924 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Intrastats overview** Revision Document id: 8925 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **VM3COP14 Documentation** Revision Document id: 9276 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7722** Audit 10 Documentation Control Viamed **Process: 7725** Audit 12 CE Files Viamed

applicable regulatory requirements, but not less than two years from the medical device release by the organization.		

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 id: 13379 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure** Revision Document id: 8672 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document id: 22684 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017 **VM3COP02 Organisation Responsibilities Viamed** Revision Document id: 17423 Date Revision:07 Sep 2016 Reviewed:07 Sep 2016 **Chart 01 System and Documentation** Revision Document id: 8675 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 02 Resource Management** Revision Document id: 8676 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **VM3COP19 Health and Safety** Revision Document id: 21800 Date Revision:05 Sep 2017 Reviewed:05 Sep 2017 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Explaination Quality Objectives** Revision Document id: 18483 Date Revision:18 Jan 2017 Reviewed:18 Jan 2017 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Explanation Control of documents** Revision Document id: 21322 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017 **How to Hold Intrastat Meetings** Revision Document id: 8928 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Chart 40 Management review plan Issues followup** Revision Document id: 22458 Date Revision:05 Oct 2017 Reviewed:05 Oct 2017 **Audit 18 Management Review Blank**	**Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7715** Audit 02 Contract Review Viamed **Process: 7833** Importance Of Effective Quality Management **Process: 27** Management Reviews And Quality Audits **Process: 7070** Management Review **Process: 7848** Review ISO Scopes **Process: 23** Company Objectives

	Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Viamed Top Level Quality Objectives** Revision Document id: 22429 Date Revision:04 Oct 2017 Reviewed:04 Oct 2017	
5.2 Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met. **Customer focus**	**Top Level Document: VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** Revision Document id: 22950 Date Revision:18 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 id: 17419 Date Revision:06 Sep 2016 Reviewed:06 Sep 2016 **Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document id: 13387 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **VM3COP20.01 Post In Distributing the Post** Revision Document id: 18641 Date Revision:10 Feb 2017 Reviewed:10 Feb 2017 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **MISC Incident Report** Revision Document id: 240 Date Revision:17 Aug 2006 Reviewed:17 Aug 2006 **How to Hold Intrastat Meetings** Revision Document id: 8928 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 04 Accounts and Finance** Revision Document id: 22086 Date Revision:17 Sep 2017 Reviewed:17 Sep 2017 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 16 Sales and Marketing** Revision Document id: 22080 Date Revision:17 Sep 2017 Reviewed:17 Sep 2017	**Process: 7** Checking Of Sales Orders **Process: 11** Distribution Of Mail **Process: 5882** Responsibility Allocation : Send Post To Humanmed **Process: 2** Answering Telephones **Process: 7715** Audit 02 Contract Review Viamed **Process: 7743** Customer Complaints Paper File **Process: 7716** Audit 03 Design Control Viamed
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;	**Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document id: 22684 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document id: 22062 Date Revision:16 Sep 2017 Reviewed:16 Sep 2017 **VM3COP00.01 Company objectives** Revision Document id: 22842 Date Revision:17 Oct 2017 Reviewed:17 Oct 2017 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10b Process Verification**	**Process: 23** Company Objectives **Process: 22** Company Policys **Process: 23** Company Objectives **Process: 7723** Audit 10b Process Verification Viamed **Process: 7833** Importance Of Effective Quality Management **Process: 7828** Review The Quality Policy Viamed

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**	Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	**Process: 7827** Review The Quality Policy VST
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 id: 13387 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **VM3COP18 Post Market Surveilance** Revision Document id: 8106 Date Revision:21 Mar 2011 Reviewed:21 Mar 2011 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Explaination Quality Objectives** Revision Document id: 18483 Date Revision:18 Jan 2017 Reviewed:18 Jan 2017 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Viamed Top Level Quality Objectives** Revision Document id: 22429 Date Revision:04 Oct 2017 Reviewed:04 Oct 2017	**Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7830** Review Q.A. Failures Report **Process: 26** Company Resources **Process: 5877** Responsibility Allocation : Review Company Data
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.	**Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document id: 21556 Date Revision:22 Aug 2017 Reviewed:11 Oct 2017 **Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document id: 22684 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Explaination Quality Objectives** Revision Document id: 18483 Date Revision:18 Jan 2017 Reviewed:18 Jan 2017 **Explanation Control of documents** Revision Document id: 21322 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017 **Route to Medical device files** Revision Document id: 18495 Date Revision:18 Jan 2017 Reviewed:18 Jan 2017	**Process: 11** Distribution Of Mail **Process: 5882** Responsibility Allocation : Send Post To Humanmed **Process: 7723** Audit 10b Process Verification Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed

Quality management system planning	**VM3COP20.01 Post In Distributing the Post** Revision Document id: 18641 Date Revision:10 Feb 2017 Reviewed:10 Feb 2017 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document id: 22062 Date Revision:16 Sep 2017 Reviewed:16 Sep 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Viamed Top Level Quality Objectives** Revision Document id: 22429 Date Revision:04 Oct 2017 Reviewed:04 Oct 2017 **VM3COP00.01 Company objectives** Revision Document id: 22842 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 perform these tasks. **Responsibility and authority**	**Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks** Revision Document id: 13379 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document id: 21556 Date Revision:22 Aug 2017 Reviewed:11 Oct 2017 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **VM3COP02 Organisation Responsibilities Viamed** Revision Document id: 17423 Date Revision:07 Sep 2016 Reviewed:07 Sep 2016 **Chart 01 System and Documentation** Revision Document id: 8675 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 02 Resource Management** Revision Document id: 8676 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Viamed Company Format Company format 1** Revision Document id: 9039 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Viamed Company Format Company format 2** Revision Document id: 9040 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Viamed Company Format Company format 3** Revision Document id: 9041 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Viamed Company Format Company format 4** Revision Document id: 9042 Date Revision:18 Oct	**Process: 7720** Audit 08 Training Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7713** Review Roles And Responsibilitys **Process: 6837** Personnel Requirements and Training

	2011 Reviewed:18 Oct 2011 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document id: 21806 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 id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017	**Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7833** Importance Of Effective Quality Management
5.5.3 Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the	**VM3COP27.01 Searching Intrastats Issues** Revision Document id: 6657 Date Revision:02 Nov 2009 Reviewed:02 Nov 2009 **Intrastats overview** Revision Document id: 8925 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	

effectiveness of the quality management system. **Internal communication**		
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, 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**	**How to Hold Intrastat Meetings** Revision Document id: 8928 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Management Review** Revision Document id: 19792 Date Revision:05 May 2017 Reviewed:05 May 2017 **Management reviews** Revision Document id: 19801 Date Revision:05 May 2017 Reviewed:05 May 2017	**Process: 7846** ISO System Management Review **Process: 27** Management Reviews And Quality Audits **Process: 7070** Management Review
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	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document id: 17419 Date Revision:06 Sep 2016 Reviewed:06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document id: 13697 Date Revision:12 May 2014 Reviewed:12 May 2014 **Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document id: 21556 Date Revision:22 Aug 2017 Reviewed:11 Oct 2017 **Top Level Document: VOP10.01 VM3COP10.01 Preventative Actions** Revision Document id: 22462 Date Revision:05 Oct	**Process: 7743** Customer Complaints Paper File **Process: 7743** Customer Complaints Paper File **Process: 7743** Customer Complaints Paper File **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative **Process: 7839** Review VIAMED Feedback - Customer Complaints **Process: 7842** Review VIAMED Product Feedback Negative **Process: 7846**

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.	2017 Reviewed:05 Oct 2017 **Chart 27 Customer Complaints Chart 27** Revision Document id: 8700 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **VM3COP18 Post Market Surveilance** Revision Document id: 8106 Date Revision:21 Mar 2011 Reviewed:21 Mar 2011 **How to Hold Intrastat Meetings** Revision Document id: 8928 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 21 Audit of Audit** Revision Document id: 9037 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	ISO System Management Review **Process: 7848** Review ISO Scopes **Process: 7849** Review Product Failures New Codes **Process: 7871** Review Exclusion From Viamed 13485:2016 And VST 9001:2015 **Process: 7837** Review External Parties Influencing The QMS VST / Viamed **Process: 7830** Review Q.A. Failures Report **Process: 7741** Review Ethical Policy **Process: 7713** Review Roles And Responsibilitys **Process: 7070** Management Review **Process: 6931** Customer Complaints **Process: 7091** Calibration Index
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; d) resource needs. **Review output**	**Issues Overview** Revision Document id: 22272 Date Revision:27 Sep 2017 Reviewed:27 Sep 2017 **VM3COP27.01 Searching Intrastats Issues** Revision Document id: 6657 Date Revision:02 Nov 2009 Reviewed:02 Nov 2009 **Management Review** Revision Document id: 19792 Date Revision:05 May 2017 Reviewed:05 May 2017 **Management reviews** Revision Document id: 19801 Date Revision:05 May 2017 Reviewed:05 May 2017 **Management reviews minutes** Revision Document id: 19803 Date Revision:05 May 2017 Reviewed:05 May 2017 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7730** Audit 20 Process Verification To Managment Viamed

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 id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017	**Process: 7723** Audit 10b Process Verification Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed
6.2 **Human resources**	**Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 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 performing work affecting product quality; b) provide training	**VM3COP12 Training** Revision Document id: 8714 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document id: 21806 Date Revision:05 Sep 2017 Reviewed:05 Sep 2017	**Process: 7720** Audit 08 Training Viamed

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.		
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	**Top Level Document: VOP 06 Measurement Control Viamed, Calibration, QA Stock** Revision Document id: 6268 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **VM3COP11 Calibration** Revision Document id: 8713 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **HSE Fire Exit / Escape Route Ground Floor plans** Revision Document id: 18653 Date Revision:14 Feb 2017 Reviewed:14 Feb 2017 **HSE Fire Exit / Escape Route Ground Floor plans Document** Revision Document id: 2558 Date Revision:01 Aug 2007 Reviewed:01 Aug 2007 **HSE Fire Risk Assessment** Revision Document id: 21790 Date Revision:04 Sep 2017 Reviewed:04 Sep 2017 **HSE Fire Safety Risk Assessment** Revision Document id: 892 Date Revision:25 Oct 2006 Reviewed:25 Oct 2006 **HSE Fire / Exit Escape route Basement floor plans** Revision Document id: 15401 Date Revision:07 Aug 2015 Reviewed:26 Sep 2016	**Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed **Process: 6855** Risk Assessment HSE **Process: 6856** Fire Alarms **Process: 7092** P.A.T. Testing **Process: 54** Responsibility Allocation : Gents Toilets **Process: 5907** Hoover Warehouse **Process: 5908** Sweep Warehouse **Process: 5909** Empty Warehouse Bins **Process: 5911** Responsibility Allocation : Clear Cardboard **Process: 5856**

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 environment and monitoring and measurement.
Records of such maintenance shall be maintained
Infrastructure

HSE Fire / Exit Escape route Ghyll House floor plans
Revision Document id: 15403 Date Revision:07 Aug 2015 Reviewed:26 Sep 2016
Ghyll House Fire Certificate
Revision Document id: 12303 Date Revision:15 Mar 2013 Reviewed:15 Mar 2013
CPM 21 Fire Exit / Escape Route Procedures
Revision Document id: 21892 Date Revision:07 Sep 2017 Reviewed:07 Sep 2017
FIRE Report Premisis
Revision Document id: 17505 Date Revision:26 Sep 2016 Reviewed:26 Sep 2016
VM3COP20.35 Ups Calculator
Revision Document id: 17149 Date Revision:05 Jul 2016 Reviewed:05 Jul 2016
VM3COP20.07 UPS Procedures
Revision Document id: 8722 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
VM3COP03.05 Procedures for customer returning goods on our UPS account number
Revision Document id: 17155 Date Revision:05 Jul 2016 Reviewed:05 Jul 2016
Explanation Employee Roles and Titles
Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017
Audit 07 Handling and Storage
Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016
Audit 09 Goods Inward and Product Identity
Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016
Audit 19 Health and Safety, Working Conditions and Building Fabric Issues
Revision Document id: 21806 Date Revision:05 Sep 2017 Reviewed:05 Sep 2017
Audit 15 Production
Revision Document id: 17384 Date Revision:03 Sep 2016 Reviewed:03 Sep 2016

Cleaning The Kitchen
Process: 7802
Clean Kitchen Sides
Process: 7803
Dishwashing
Process: 7804
Sweep Kitchen Floor
Process: 7805
Empty Kitchen Bins
Process: 7806
Watering Plants
Process: 56
Warehouse Outside Heating Guard
Process: 5919
Check Out Side Drain
Process: 5921
Clearing Water Downstairs
Process: 7120
General Maintenance Requirements
Process: 7742
Boiler Check
Process: 7756
Carbon Monoxide Alarm
Process: 7820
North Yorkshire Council Waste Tranfer
Process: 7821
Controlled Waste Description And Transfer
Process: 7835
Electrics Need Checking
Process: 7836
Central Heating For Winter
Process: 7713
Review Roles And Responsibilitys
Process: 7845
7.1.4 Environment Of Operations
Process: 45
Responsibility Allocation : Main Server Status
Process: 48
Responsibility Allocation : Internet
Process: 52
Software Verification Clear Down Backup Emails
Process: 5903
Responsibility Allocation : Weather Station
Process: 5939
Responsibility Allocation : Email ISP Routing
Process: 7121
Responsibility Allocation :

		General Computer Maintenance **Process: 7129** Intrastats Cross Reference Database Tables Updates **Process: 7672** Off Site Backup **Process: 7704** Responsibility Allocation : Computer Failure Diagnostics **Process: 7850** Software Validation Scan In Correct Product **Process: 7851** Software Validation Scan Un-QA Product To Order **Process: 7852** Software Validation Expired Stock **Process: 7853** Software Validation Non Sell Able Shelf **Process: 7854** Software Validation In Production List **Process: 7855** Software Validation - Production Lists **Process: 7856** Software Validation Unchecked Orders **Process: 7857** Software Validation Stock Tracking Check **Process: 7858** Software Validation Attempt To QA Some Stock **Process: 7861** Software Validation Of Training Documents Forced Reading
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.	**Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure** Revision Document id: 8672 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **CPM 15 Disciplinary Procedures** Revision Document id: 8360 Date Revision:07 Jun 2011 Reviewed:07 Jun 2011 **CPM 16 Dress Code** Revision Document id: 7055 Date Revision:26 Apr	**Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7720** Audit 08 Training Viamed **Process: 7729** Audit 19 Health And Saftey Viamed **Process: 56**

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 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**	2010 Reviewed:22 Jul 2014 **CPM 25 Health and Safety Policy Viamed** Revision Document id: 14332 Date Revision:25 Sep 2014 Reviewed:04 Sep 2017 **CPM 39 Smoking Policy** Revision Document id: 6782 Date Revision:15 Feb 2010 Reviewed:15 Feb 2010 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document id: 21806 Date Revision:05 Sep 2017 Reviewed:05 Sep 2017	Warehouse Outside Heating Guard **Process: 5919** Check Out Side Drain **Process: 5921** Clearing Water Downstairs **Process: 7120** General Maintenance Requirements **Process: 7742** Boiler Check **Process: 7756** Carbon Monoxide Alarm **Process: 7820** North Yorkshire Council Waste Tranfer **Process: 7821** Controlled Waste Description And Transfer **Process: 7835** Electrics Need Checking **Process: 7836** Central Heating For Winter **Process: 7864** ESD Work Stations **Process: 7873** On Site Environment Review **Process: 54** Responsibility Allocation : Gents Toilets **Process: 5906** Empty Paper Bins **Process: 5907** Hoover Warehouse **Process: 5908** Sweep Warehouse **Process: 5909** Empty Warehouse Bins **Process: 5910** Clean Duckets **Process: 5911** Responsibility Allocation : Clear Cardboard **Process: 7698** Clean Toilets
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	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document id: 22838 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017 **Viamed Environment Policy Inc WEEE** Revision Document id: 17472 Date Revision:14 Sep 2016 Reviewed:30 Sep 2017 **Wee Registration Viamed** Revision Document id: 13264 Date Revision:09 Jan 2014 Reviewed:09 Jan 2014 **Wee Registration Vandagraph** Revision Document id: 13265 Date Revision:09 Jan	**Process: 39** Enviromental Policy Document Review **Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7714** Audit 01 Picking Packing Viamed **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed

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**	2014 Reviewed:09 Jan 2014 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 01 Picking packing** Revision Document id: 7664 Date Revision:14 Feb 2011 Reviewed:14 Feb 2011 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document id: 21806 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	**VM3COP24.00 Viamed Overall Risk Analysis Program** Revision Document id: 23006 Date Revision:19 Oct 2017 Reviewed:19 Oct 2017 **VM3COP27.12 Clinical Evaluation Risk assessment Technical Files** Revision Document id: 15453 Date Revision:11 Aug 2015 Reviewed:11 Aug 2015 **VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document id: 17824 Date Revision:03 Nov 2016 Reviewed:03 Nov 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7732** Audit 22 Post Market Survellance Viamed **Process: 7716** Audit 03 Design Control Viamed

appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971. **Planning of product realization**		
7.2 **Customer-related processes**		
7.2.1 The organization shall determine: a) requirements specified by the customer, including the requirements for	**Top Level Document: VOP 14 Servicing Out of Building Servicing** Revision Document id: 8669 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Top Level Document: VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** Revision Document id: 22950 Date Revision:18 Oct	**Process: 7732** Audit 22 Post Market Survellance Viamed **Process: 7715** Audit 02 Contract Review Viamed **Process: 7825**

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**	2017 Reviewed:18 Oct 2017 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **VM3COP20.31 Export Order Processing** Revision Document id: 22016 Date Revision:15 Sep 2017 Reviewed:15 Sep 2017 **VM3COP03.01 Order Processing Priorities** Revision Document id: 20049 Date Revision:15 May 2017 Reviewed:15 May 2017 **VM3COP20.30 UK Order Processing** Revision Document id: 22527 Date Revision:11 Oct 2017 Reviewed:11 Oct 2017 **VM3COP03.07 Humanmed Order Checking** Revision Document id: 22266 Date Revision:27 Sep 2017 Reviewed:27 Sep 2017 **VM3COP03.08 Humanmed Order Processing** Revision Document id: 22369 Date Revision:29 Sep 2017 Reviewed:29 Sep 2017 **VM3COP20.32 Order Checking** Revision Document id: 17152 Date Revision:05 Jul 2016 Reviewed:05 Jul 2016 **Infant Resuscitation Cabinet - Training Assessment Form** Revision Document id: 14334 Date Revision:25 Sep 2014 Reviewed:25 Sep 2014 **Oxygen Sensor Training Powerpoint** Revision Document id: 15736 Date Revision:24 Sep 2015 Reviewed:25 Oct 2016 **Oxygen Sensor Training Video** Revision Document id: 15737 Date Revision:24 Sep 2015 Reviewed:24 Sep 2015 **Resuscitation Unit and TC400 Training Information Resuscitation Cabinet Training** Revision Document id: 4111 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 id: 4122 Date Revision:09 Jul 2008 Reviewed:09 Jul 2008 **Single Use Surgical Training Information certificates** Revision Document id: 20220 Date Revision:19 May 2017 Reviewed:19 May 2017 **SpO2 800 series Training Information** Revision Document id: 12687 Date Revision:02 Jul 2013 Reviewed:02 Jul 2013 **TECcare Training Material** Revision Document id: 11826 Date Revision:11 Jun 2012 Reviewed:11 Jun 2012 **Temperature Probe Training Material** Revision Document id: 18169 Date Revision:05 Dec 2016 Reviewed:05 Dec 2016	Responsibility Allocation : Order Picking **Process: 5** Processing Of Sales Orders **Process: 7825** Responsibility Allocation : Order Picking **Process: 7825** Responsibility Allocation : Order Picking **Process: 7** Checking Of Sales Orders **Process: 7734** Humanmed Order Processing **Process: 5** Processing Of Sales Orders **Process: 7734** Humanmed Order Processing **Process: 7825** Responsibility Allocation : Order Picking

	Tom Thumb Training Information Revision Document id: 7880 Date Revision:07 Mar 2011 Reviewed:07 Mar 2011 **Tom Thumb Training Information 2009** Revision Document id: 15644 Date Revision:16 Sep 2015 Reviewed:16 Sep 2015 **Tom Thumb Training Information Training Manual Training Information** Revision Document id: 2973 Date Revision:31 Jan 2008 Reviewed:31 Jan 2008 **Tom Thumb Training Information Training V1.1** Revision Document id: 15641 Date Revision:16 Sep 2015 Reviewed:16 Sep 2015 **Training information Infant Resusitation Unit** Revision Document id: 8665 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **VM-2500 Product Training Materials - Frequently Asked Questions** Revision Document id: 6967 Date Revision:17 Mar 2010 Reviewed:17 Mar 2010 **VM-2500 Product Training Materials Capnography Product Application Notes** Revision Document id: 6749 Date Revision:08 Feb 2010 Reviewed:08 Feb 2010 **VM-2500 Product Training Materials Capnography Product Presentation MASTER** Revision Document id: 6750 Date Revision:08 Feb 2010 Reviewed:08 Feb 2010 **VM-2500 Product Training Materials Mainstream or Sidestream Capnography** Revision Document id: 6753 Date Revision:08 Feb 2010 Reviewed:08 Feb 2010 **VM3COPxx Viamed Policy on End User Training UK** Revision Document id: 9289 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 01 Picking packing** Revision Document id: 7664 Date Revision:14 Feb 2011 Reviewed:14 Feb 2011 **Audit 16 Sales and Marketing** Revision Document id: 22080 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 prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of	**Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 16 Sales and Marketing**	**Process: 7715** Audit 02 Contract Review Viamed **Process: 7724** Audit 11 Repairs And Service Viamed **Process: 7723** Audit 10b Process Verification Viamed **Process: 7722** Audit 10 Documentation Control Viamed

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**	Revision Document id: 22080 Date Revision:17 Sep 2017 Reviewed:17 Sep 2017	

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 communicate with regulatory authorities in accordance with applicable regulatory requirements. **Communication**	**Top Level Document: VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** Revision Document id: 22950 Date Revision:18 Oct 2017 Reviewed:18 Oct 2017 **Top Level Document: vop VM3COP20.11 Non-Conformances** Revision Document id: 21314 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017 **Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document id: 17419 Date Revision:06 Sep 2016 Reviewed:06 Sep 2016 **VM3COP27.31 Processing Proforma Invoices and Quotations** Revision Document id: 20584 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **VM3COP20.05 New Orders - How to enter into Opera Viamed** Revision Document id: 13695 Date Revision:12 May 2014 Reviewed:12 May 2014 **VM3COP20.32 Order Checking** Revision Document id: 17152 Date Revision:05 Jul 2016 Reviewed:05 Jul 2016 **VM3COP20.49 Informing Customers of Price Amends** Revision Document id: 18357 Date Revision:05 Jan 2017 Reviewed:05 Jan 2017 **VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork** Revision Document id: 13968 Date Revision:23 May 2014 Reviewed:23 May 2014 **VM3COP20.22 Quoting Customer Special prices.** Revision Document id: 15613 Date Revision:09 Sep 2015 Reviewed:09 Sep 2015 **VM3COP10.02 Product Recall locate products out in the Field** Revision Document id: 13158 Date Revision:14 Nov 2013 Reviewed:14 Nov 2013 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 16 Sales and Marketing** Revision Document id: 22080 Date Revision:17 Sep 2017 Reviewed:17 Sep 2017 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 01 Picking packing** Revision Document id: 7664 Date Revision:14 Feb 2011 Reviewed:14 Feb 2011 **Audit 04 Accounts and Finance**	**Process: 2** Answering Telephones **Process: 7710** Responsibility Allocation : Proforma And Quote Processing **Process: 7825** Responsibility Allocation : Order Picking **Process: 6828** Non Conformance Issues **Process: 7743** Customer Complaints Paper File **Process: 7743** Customer Complaints Paper File **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed **Process: 7715** Audit 02 Contract Review Viamed

	Revision Document id: 22086 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 id: 9182 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **BSI Technical File Design File Requirements Dosier** Revision Document id: 4959 Date Revision:29 Dec 2008 Reviewed:29 Dec 2008 **CE & Design files re-organisation** Revision Document id: 9085 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Chart 04 Design and Development** Revision Document id: 8678 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 17 Design Repairs** Revision Document id: 8690 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 30 System Design Plan** Revision Document id: 8703 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **New Project Design File Content** Revision Document id: 9093 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **VM3COP16 Design and Design Changes** Revision Document id: 7396 Date Revision:10 Jan 2011 Reviewed:10 Jan 2011 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed **Process: 7723** Audit 10b Process Verification Viamed
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	**VM3COP16 Design and Design Changes** Revision Document id: 7396 Date Revision:10 Jan 2011 Reviewed:10 Jan 2011 **VM3COP27.07 Project Manager** Revision Document id: 12734 Date Revision:11 Jul 2013 Reviewed:11 Jul 2013 **VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document id: 17824 Date Revision:03 Nov 2016 Reviewed:03 Nov 2016 **VM3COP27.12 Clinical Evaluation Risk assessment Technical Files** Revision Document id: 15453 Date Revision:11 Aug 2015 Reviewed:11 Aug 2015 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016	**Process: 7716** Audit 03 Design Control Viamed **Process: 7723** Audit 10b Process Verification Viamed **Process: 7720** Audit 08 Training Viamed

planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development; e) the methods to ensure traceability of design and development outputs to design and development inputs; f) the resources needed including necessary competence of personnel **Design and development planning**	**Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 12 CE Files** Revision Document id: 17299 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	**Top Level Document: VOP 17 Design Research and Development** Revision Document id: 9182 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7716** Audit 03 Design Control Viamed **Process: 7722** Audit 10 Documentation Control Viamed **Process: 7723** Audit 10b Process Verification Viamed

from previous similar designs; e) other requirements essential for design and development of the product and processes. These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other. NOTE Further information can be found in IEC 62366–1. **Design and development inputs**		
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	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed

release. Records of the design and development outputs shall be maintained (see 4.2.5). **Design and development outputs**		
7.3.5 **Design and development review**	**Audit 12 CE Files** Revision Document id: 17299 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 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).	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed
7.3.6 Design and development verification shall be performed in	**Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	

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**		
7.3.7 **Design and development validation**	**Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	
7.3.7 Design and development validation shall be performed in accordance with planned and documented arrangements to	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed **Process: 7723** Audit 10b Process Verification Viamed

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).		
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 id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7716** Audit 03 Design Control Viamed **Process: 7722** Audit 10 Documentation Control Viamed
7.3.9 The organization shall document	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016	**Process: 7716** Audit 03 Design Control Viamed

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 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7726** Audit 14 Complaints And Corrective Actions Viamed
7.3.10 The organization shall maintain a design and development file for each medical device type or medical device family. This	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7722** Audit 10 Documentation Control Viamed **Process: 7716** Audit 03 Design Control Viamed

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**		
7.4 **Purchasing**	**VM3COP04 Purchasing / suppliers** Revision Document id: 15473 Date Revision:14 Aug 2015 Reviewed:14 Aug 2015 **VM3COP20.29 Checking the Purchase Order Log** Revision Document id: 20588 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **VM3COP27.34 Sending Purchase Orders to Suppliers** Revision Document id: 17070 Date Revision:22 Jun 2016 Reviewed:22 Jun 2016 **VM3COP04.01 QC06 Supplier Questionnaire ISO Questionnaire Viamed Blank** Revision Document id: 21304 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017	**Process: 5850** Purchase Order Log **Process: 7707** Send Purchase Orders To Suppliers
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 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	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016 **Audit 04 Accounts and Finance** Revision Document id: 22086 Date Revision:17 Sep 2017 Reviewed:17 Sep 2017	**Process: 7717** Audit 05 Purchasing Suppliers Viamed **Process: 7725** Audit 12 CE Files Viamed

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**		
7.4.2 Purchasing information shall describe or reference the product to be purchased, including as appropriate: a) product specifications;	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7717** Audit 05 Purchasing Suppliers Viamed

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 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	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016	**Process: 7717** Audit 05 Purchasing Suppliers Viamed **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed

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**		
7.5 **Production and service provision**		
7.5.1 Production and service provision shall be planned, carried out, monitored and controlled to ensure that	**VM3COP20.37 Generating a New Service Visit** Revision Document id: 17116 Date Revision:28 Jun 2016 Reviewed:28 Jun 2016 **Audit 06 Calibration** Revision Document id: 17282 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 01 Picking packing** Revision Document id: 7664 Date Revision:14 Feb	**Process: 7714** Audit 01 Picking Packing Viamed **Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7725** Audit 12 CE Files Viamed

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**	2011 Reviewed:14 Feb 2011 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 15 Production** Revision Document id: 17384 Date Revision:03 Sep 2016 Reviewed:03 Sep 2016 **Audit 24 Service Logs** Revision Document id: 14795 Date Revision:20 Feb 2015 Reviewed:20 Feb 2015 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016	**Process: 7727** Audit 15 Production Viamed
7.5.2 The organization shall document requirements for cleanliness of	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document id: 22838 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017 **Audit 05 Purchasing suppliers**	**Process: 7717** Audit 05 Purchasing Suppliers Viamed **Process: 7719**

product or contamination control of product if: a) product is cleaned by the organization prior to sterilization or its use; b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use; c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; e) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process. **Cleanliness of product**	Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	Audit 07 Handling And Storage Viamed
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	**Resuscitation Unit and TC400 Maintenance** **TC400 Installation Instructions** Revision Document id: 8155 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 id: 8178 Date Revision:24 Mar 2011 Reviewed:24 Mar 2011 **Resuscitation Unit Instructions for Use / User Manual Nufer Wall Mount Installation** Revision Document id: 1312 Date Revision:19 Mar 2007 Reviewed:19 Mar 2007 **VM3COP51.20 Resuscitation Cabinet Installation Instructions** Revision Document id: 18221 Date Revision:12 Dec 2016 Reviewed:12 Dec 2016	**Process: 7717** Audit 05 Purchasing Suppliers Viamed

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**	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 24 Service Logs** Revision Document id: 14795 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	**VM3COP20.27 Annual Services for Resuscitation Cabinets** Revision Document id: 16987 Date Revision:25 May 2016 Reviewed:25 May 2016 **VM3COP20.37 Generating a New Service Visit** Revision Document id: 17116 Date Revision:28 Jun 2016 Reviewed:28 Jun 2016 **VM3COP50.12 Quality Control / Service Checks Tom Thumb** Revision Document id: 15367 Date Revision:05 Aug 2015 Reviewed:05 Aug 2015 **VM3COP50.13 Quality Control Tom Thumb** Revision Document id: 15365 Date Revision:05 Aug 2015 Reviewed:05 Aug 2015 **Audit 24 Service Logs** Revision Document id: 14795 Date Revision:20 Feb 2015 Reviewed:20 Feb 2015 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 5857** Customer Service Logs **Process: 7722** Audit 10 Documentation Control Viamed

4.2.5). **Servicing activities**		
7.5.5 The organization shall maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records shall be traceable to each production batch of medical devices. **Particular requirements for sterile medical devices**	**Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO** Revision Document id: 22838 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017	**Process: 7722** Audit 10 Documentation Control Viamed **Process: 7717** Audit 05 Purchasing Suppliers Viamed
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;	**VM3COP18 Post Market Surveilance** Revision Document id: 8106 Date Revision:21 Mar 2011 Reviewed:21 Mar 2011 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 24 Service Logs** Revision Document id: 14795 Date Revision:20 Feb 2015 Reviewed:20 Feb 2015 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	

c) use of specific methods, procedures and acceptance criteria; d) as appropriate, statistical techniques with rationale for sample sizes e) requirements for records (see 4.2.5); f) revalidation, including criteria for revalidation; g) approval of changes to the processes. The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).			

Validation of processes for production and service provision		
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 id: 22838 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	**Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document id: 13387 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	

monitoring and measurement requirements throughout product realization. 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**	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	
7.5.9 **Traceability**	**VM3COP14.01 Disposition of Documents / Records.** Revision Document id: 15464 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	**VM3COP14.01 Disposition of Documents / Records.** Revision Document id: 15464 Date Revision:14 Aug 2015 Reviewed:14 Aug 2015 **VM3COP23.00 EAN13 Barcodes to Stock and the Online Databases** Revision Document id: 8596 Date Revision:25 Aug 2011 Reviewed:25 Aug 2011 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10 Documentation Control**	

records to be maintained (see 4.2.5). **General**	Revision Document id: 17324 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 id: 22838 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	**VM3COP09 Repairs** Revision Document id: 8712 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **VM3COP20.03 Repair Procedures** Revision Document id: 13703 Date Revision:13 May 2014 Reviewed:13 May 2014 **VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork** Revision Document id: 13968 Date Revision:23 May 2014 Reviewed:23 May 2014 **VM3COP20.47 Collecting Repair Paperwork** Revision Document id: 17485 Date Revision:15 Sep 2016 Reviewed:15 Sep 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep	**Process: 7684** Repairs Ready For Quote **Process: 7685** Repairs Ready For Invoice **Process: 5891** Processing Of Repair Quotes And Orders **Process: 7693** Collect Repair Filing From Warehouse

use, the organization shall report this to the customer and maintain records (see 4.2.5). **Customer property**	2016 Reviewed:05 Sep 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 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 id: 13703 Date Revision:13 May 2014 Reviewed:13 May 2014 **VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork** Revision Document id: 13968 Date Revision:23 May 2014 Reviewed:23 May 2014 **Audit 01 Picking packing** Revision Document id: 7664 Date Revision:14 Feb 2011 Reviewed:14 Feb 2011 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7684** Repairs Ready For Quote **Process: 7685** Repairs Ready For Invoice **Process: 5891** Processing Of Repair Quotes And Orders
7.6 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring	**Top Level Document: VOP 06 Measurement Control VST, Calibration, QA Stock** Revision Document id: 13385 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Top Level Document: VOP 06 Measurement Control Viamed, Calibration, QA Stock** Revision Document id: 6268 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009	

equipment needed to provide evidence of conformity of product to 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	**VM3COP11 Calibration** Revision Document id: 8713 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Explanation Control of documents** Revision Document id: 21322 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017 **Audit 06 Calibration** Revision Document id: 17282 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017		

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 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. This shall include determination of appropriate methods, including statistical techniques, and the extent of their use. **General**	**Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document id: 17824 Date Revision:03 Nov 2016 Reviewed:03 Nov 2016 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **VM3COP13 Audits** Revision Document id: 8715 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011	**Process: 7714** Audit 01 Picking Packing Viamed **Process: 7715** Audit 02 Contract Review Viamed **Process: 7716** Audit 03 Design Control Viamed **Process: 7717** Audit 05 Purchasing Suppliers Viamed **Process: 7718** Audit 06 Calibration Viamed **Process: 7720** Audit 08 Training Viamed **Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed **Process: 7722** Audit 10 Documentation Control Viamed **Process: 7724** Audit 11 Repairs And Service Viamed **Process: 7723**

		Audit 10b Process Verification Viamed **Process: 7725** Audit 12 CE Files Viamed **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed **Process: 7727** Audit 15 Production Viamed **Process: 7728** Audit 17 Internal Audits Viamed **Process: 7729** Audit 19 Health And Saftey Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7731** Audit 21 Audit Of Audit Viamed **Process: 7732** Audit 22 Post Market Survellance Viamed **Process: 7733** Audit 23 Analysis Of Data Viamed
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 document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well	**VM3COP27.11 Performing a Technical File PMS and risk assessment** Revision Document id: 17824 Date Revision:03 Nov 2016 Reviewed:03 Nov 2016 **Management Review** Revision Document id: 19792 Date Revision:05 May 2017 Reviewed:05 May 2017 **Management reviews** Revision Document id: 19801 Date Revision:05 May 2017 Reviewed:05 May 2017 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	

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**		
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	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document id: 17419 Date Revision:06 Sep 2016 Reviewed:06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document id: 13697 Date Revision:12 May 2014 Reviewed:12 May 2014 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7743** Customer Complaints Paper File **Process: 7743** Customer Complaints Paper File

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 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	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document id: 17419 Date Revision:06 Sep 2016 Reviewed:06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document id: 13697 Date Revision:12 May 2014 Reviewed:12 May 2014 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **MHRA Correspondence / RG2 Devices list** Revision Document id: 14763 Date Revision:12 Feb 2015 Reviewed:12 Feb 2015 **MHRA Appendix A / Appendix B Class 1 Device Codes** Revision Document id: 4798 Date Revision:24 Oct 2008 Reviewed:24 Oct 2008	**Process: 7743** Customer Complaints Paper File **Process: 7743** Customer Complaints Paper File

maintained (see 4.2.5). **Reporting to regulatory authorities**	**CE Guidance 19 Own Brand MHRA position obl** Revision Document id: 3656 Date Revision:29 Apr 2008 Reviewed:29 Apr 2008	
8.2.4 The organization shall conduct internal audits at planned intervals to determine whether the quality 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	**Audit 01 Picking packing** Revision Document id: 7664 Date Revision:14 Feb 2011 Reviewed:14 Feb 2011 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 06 Calibration** Revision Document id: 17282 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 15 Production** Revision Document id: 17384 Date Revision:03 Sep 2016 Reviewed:03 Sep 2016 **Audit 17 Internal Audits** Revision Document id: 8798 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document id: 21806 Date Revision:05 Sep 2017 Reviewed:05 Sep 2017 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun	**Process: 7714** Audit 01 Picking Packing Viamed **Process: 7715** Audit 02 Contract Review Viamed **Process: 7716** Audit 03 Design Control Viamed **Process: 7717** Audit 05 Purchasing Suppliers Viamed **Process: 7718** Audit 06 Calibration Viamed **Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7720** Audit 08 Training Viamed **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed **Process: 7722** Audit 10 Documentation Control Viamed **Process: 7723** Audit 10b Process Verification Viamed **Process: 7725** Audit 12 CE Files Viamed **Process: 7724** Audit 11 Repairs And Service Viamed **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed **Process: 7727** Audit 15 Production Viamed **Process: 7728** Audit 17 Internal Audits Viamed **Process: 7729** Audit 19 Health And Saftey Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7731** Audit 21 Audit Of Audit Viamed **Process: 7732** Audit 22 Post Market Survellance Viamed

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 can be found in ISO 19011. **Internal audit**	2017 Reviewed:13 Jun 2017 **Audit 21 Audit of Audit** Revision Document id: 9037 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 24 Service Logs** Revision Document id: 14795 Date Revision:20 Feb 2015 Reviewed:20 Feb 2015 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **VM3COP13 Audits** Revision Document id: 8715 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Audit Schedule** Revision Document id: 13027 Date Revision:21 Jan 2013 Reviewed:21 Jan 2013 **Audit 04 Accounts and Finance** Revision Document id: 22086 Date Revision:17 Sep 2017 Reviewed:17 Sep 2017	**Process: 7733** Audit 23 Analysis Of Data Viamed
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,	**Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	

correction and corrective action shall be taken, as appropriate. **Monitoring and measurement of processes**		
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 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	**VM3COP11 Calibration** Revision Document id: 8713 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **VM3COP29 Production** Revision Document id: 8727 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 15 Production** Revision Document id: 17384 Date Revision:03 Sep 2016 Reviewed:03 Sep 2016	

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 id: 17419 Date Revision:06 Sep 2016 Reviewed:06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document id: 13697 Date Revision:12 May 2014 Reviewed:12 May 2014 **Top Level Document: vop VM3COP20.11 Non-Conformances** Revision Document id: 21314 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017 **VM3COP10.02 Product Recall locate products out in the Field** Revision Document id: 13158 Date Revision:14 Nov 2013 Reviewed:14 Nov 2013 **Issues Overview** Revision Document id: 22272 Date Revision:27 Sep 2017 Reviewed:27 Sep 2017 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7743** Customer Complaints Paper File **Process: 7743** Customer Complaints Paper File **Process: 6828** Non Conformance Issues

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 id: 21314 Date Revision:06 Aug 2017 Reviewed:06 Aug 2017 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 07 Handling and Storage** Revision Document id: 17316 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	**Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	

taken shall be maintained (see 4.2.5). The organization shall document procedures for issuing advisory notices in 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 id: 6271 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	
8.4 The organization shall document	**Top Level Document: VOP 13 Process Monitoring, System Reviews, Audits, Management Review**	

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; 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	Revision Document id: 22946 Date Revision:18 Oct 2017 Reviewed:18 Oct 2017 **Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 17 Internal Audits** Revision Document id: 8798 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 24 Service Logs** Revision Document id: 14795 Date Revision:20 Feb 2015 Reviewed:20 Feb 2015		

(see 4.2.5). **Analysis of data**		
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 id: 22462 Date Revision:05 Oct 2017 Reviewed:05 Oct 2017 **Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document id: 6275 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 06 Calibration** Revision Document id: 17282 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 23 Analysis of Data** Revision Document id: 20567 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 21 Audit of Audit** Revision Document id: 9037 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	**Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document id: 6275 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	

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 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:	**Top Level Document: VOP10.01 VM3COP10.01 Preventative Actions** Revision Document id: 22462 Date Revision:05 Oct 2017 Reviewed:05 Oct 2017 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7839** Review VIAMED Feedback - Customer Complaints

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**		