

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

Version Date: 09 Jun 2021

Listing of Current Sections

Section	Documents related	Processes Direct Links
4 Quality management system		
4.1 Quality management system	Top Level Document: QMS Route Map Viamed Ltd ISO13485_2016 Revision Document ID60725 **Date Revision 25 May 2021 Reviewed 25 May 2021 Top Level Document: Viamed ISO 13485:2016 Scope Revision Document ID31634 Date Revision 14 Nov 2019 Reviewed 28 Sep 2020 Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO Revision Document ID41667 Date Revision 11 Aug 2020 Reviewed 11 Aug 2020 BS5750 Viamed Revision Document ID21353 Date Revision 10 Aug 2017 Reviewed 10 Aug 2017 BS EN ISO 13485-2016 Revision Document ID19400 Date Revision 27 Mar 2017 Reviewed 27 Mar 2017 Chart 40 Management review plan Issues followup Revision Document ID22458 Date Revision 05 Oct 2017	

	Reviewed 05 Oct 2017 Chart 42 Processes, Tasks and Audits Review Revision Document ID23559 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Chart 43 Processes and Intrastats Revision Document ID23561 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Intrastats overview Revision Document ID23567 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Issues Overview Revision Document ID23112 Date Revision 22 Oct 2017 Reviewed 22 Oct 2017 Document Index Overview Revision Document ID8047 Date Revision 17 Mar 2011 Reviewed 17 Mar 2011	
4.1.1 The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.	Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control Revision Document ID30999 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: Viamed ISO 13485:2016 Scope Revision Document ID31634 Date Revision 14 Nov 2019 Reviewed 28 Sep 2020 Audit 10 Documentation Control Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020	Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016

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
 ID27474

Date Revision 20 Sep 2018

Reviewed 20 Sep 2018

Explanation Employee
Roles and Titles

Revision Document
 ID22144

Date Revision 20 Sep 2017

Reviewed 20 Sep 2017

Chart 00 System Model

Revision Document ID8674

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 01 System and
Documentation

Revision Document ID8675

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 02 Resource
Management

Revision Document ID8676

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 03 Customer
Requirements

Revision Document ID8677

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 04 Design and
Development

Revision Document ID8678

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 05 Product
Realisation

Revision Document ID8679

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 06 General Process
Control

Revision Document ID8680

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 07 Measurement
and Analysis

Revision Document ID8681

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 08 Correction and
Prevention

Revision Document ID8682

Date Revision 12 Oct 2011

Process: 7743

Customer Complaints Paper File 26 Sep 2016

Process: 7723

Audit 10b Process Verification Viamed 24 Aug 2016

Process: 7725

Audit 12 CE Files Viamed 24 Aug 2016

Reviewed 12 Oct 2011

Chart 09 Management System

Revision Document ID8683

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 10 Documentation

Revision Document ID8684

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 11 Provision of Resources

Revision Document ID8685

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 12 Infrastructure and Environment

Revision Document ID8686

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 13 Sales Orders

Revision Document ID8687

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 15 Purchasing

Revision Document ID8688

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 16 Internal Audits

Revision Document ID8689

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 17 Design Repairs

Revision Document ID8690

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 18 Calibration

Revision Document ID8691

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 19 HSE Risk

Assesments

Revision Document ID8692

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 20 Production

Revision Document ID8693

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 21 Repairs

Revision Document ID8694

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 22 Stock Control

Revision Document ID8695

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 23 Picking and

Packing

Revision Document ID8696

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 24 Goods Inwards

Revision Document ID8697

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 25 Inspection and Test

Revision Document ID8698

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 26 Data Analysis

Revision Document ID8699

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 27 Customer Complaints Chart 27

Revision Document ID8700

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 28 Quarantine and Hold

Revision Document ID8701

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 29 Sales Acquisition

Revision Document ID8702

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 30 System Design Plan

Revision Document ID8703

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 31 Chart Interfaces

Revision Document ID8704

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 32 Generic Sales Process

Revision Document ID8705

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 33 Launch of a new product

Revision Document ID8706

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 34 Process Teams Org Chart

Revision Document ID8707

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Audit 20 Process verification to Managment

Revision Document

	ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	
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).	Top Level Document: VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data Revision Document ID53797 Date Revision 16 Feb 2021 Reviewed 16 Feb 2021 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 VM3COP27.01 Searching Intrastats Issues Revision Document ID6657 Date Revision 02 Nov 2009 Reviewed 02 Nov 2009 VM3COP27.17 Complete Auto_calender Issues Revision Document ID16995 Date Revision 26 May 2016 Reviewed 26 May 2016 Issues Overview Revision Document ID23112 Date Revision 22 Oct 2017 Reviewed 22 Oct 2017 Intrastats overview Revision Document ID23567 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Employee Roles Revision Document ID20125 Date Revision 16 May 2017 Reviewed 16 May 2017 Employee roles Example Process Revision Document ID20129 Date Revision 16 May 2017 Reviewed 16 May 2017 VM3COP27.02 Collecting Emails and Distributing Revision Document ID20131 Date Revision 16 May 2017 Reviewed 16 May 2017 Employee Roles Individual	Process: 27 Management Reviews And Quality Audits 16 Feb 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016 Process: 5889 Responsibility Allocation : Audit And Task - Audit 24 Feb 2016 Process: 7714 Audit 01 Picking Packing Viamed 24 Aug 2016 Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016 Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 Process: 7718 Audit 06 Calibration Viamed 24 Aug 2016 Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016 Process: 7720 Audit 08 Training Viamed 24 Aug 2016 Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7724 Audit 11 Repairs And Service Viamed 24 Aug 2016 Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016 Process: 7726 Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 Process: 7727 Audit 15 Production Viamed 24 Aug 2016 Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016 Process: 7729 Audit 19 Health And Saftey Viamed 24 Aug 2016 Process: 7731 Audit 21 Audit Of Audit Viamed 24 Aug 2016 Process: 7732

	Processes Revision Document ID20127 Date Revision 16 May 2017 Reviewed 16 May 2017 Audit 18 Management Review Revision Document ID41388 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	Audit 22 Post Market Surveillance Viamed 24 Aug 2016 Process: 7733 Audit 23 Analysis Of Data Viamed 24 Aug 2016 Process: 26 Company Resources 16 Feb 2016
4.1.4 For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.	Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 18 Management Review Revision Document ID41388 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Issues Overview Revision Document ID23112 Date Revision 22 Oct 2017 Reviewed 22 Oct 2017 Employee Roles Revision Document ID20125 Date Revision 16 May 2017 Reviewed 16 May 2017 Employee roles Example Process Revision Document ID20129 Date Revision 16 May 2017 Reviewed 16 May 2017 Employee Roles Individual Processes Revision Document ID20127 Date Revision 16 May 2017 Reviewed 16 May 2017 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017	Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016

	Explanation Employee Roles Titles Responsibilitys Processes and Repeating Tasks Monitoring Revision Document ID22287 Date Revision 27 Sep 2017 Reviewed 27 Sep 2017 Chart 43 Processes and Intrastats Revision Document ID23561 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Chart 42 Processes, Tasks and Audits Review Revision Document ID23559 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Chart 40 Management review plan Issues followup Revision Document ID22458 Date Revision 05 Oct 2017 Reviewed 05 Oct 2017	
4.1.5 For each quality management system process, the organization shall: When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The 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.	Top Level Document: VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns Revision Document ID31084 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 05 Purchasing suppliers Revision Document ID33536 Date Revision 15 Mar 2020 Reviewed 15 Mar 2020	Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
4.1.6 For each quality management system process, the organization shall: The organization shall	Top Level Document: Audit 27 Software Validation Revision Document ID53611	Process: 7850 Software Validation Scan In Correct Product 01 Oct 2017 Process: 7851 Software Validation Scan Un-QA Product To

document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).	Date Revision 11 Feb 2021 Reviewed 11 Feb 2021 Top Level Document: VOP 27 Software Validation Revision Document ID31064 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Intrastats Amendment Log Revision Document ID20136 Date Revision 16 May 2017 Reviewed 16 May 2017 Validation of Intrastats Revision Document ID20140 Date Revision 16 May 2017 Reviewed 16 May 2017	Order 01 Oct 2017 Process: 7852 Software Validation Expired Stock 01 Oct 2017 Process: 7853 Software Validation Non Sell Able Shelf 01 Oct 2017 Process: 7854 Software Validation In Production List 01 Oct 2017 Process: 7855 Software Validation - Production Lists 01 Oct 2017 Process: 7856 Software Validation Unchecked Orders 01 Oct 2017 Process: 7857 Software Validation Stock Tracking Check 01 Oct 2017 Process: 7858 Software Validation Attempt To QA Some Stock 01 Oct 2017 Process: 7861 Software Validation Of Training Documents Forced Reading 03 Oct 2017 Process: 7865 Software Validation Conflicting Audits 07 Oct 2017 Process: 7870 Software Validation Non Conformance Product Risk Feedback Loop 15 Oct 2017
4.2 Documentation requirements	Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control Revision Document ID30999 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 10 Documentation Control Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020	
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	Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives Revision Document ID22684 Date Revision 16 Oct 2017 Reviewed 22 Sep 2020 Top Level Document: VOP 01 Documentation /	Process: 23 Company Objectives 16 Feb 2016 Process: 22 Company Policies 16 Feb 2016 Process: 23 Company Objectives 16 Feb 2016 Process: 7730 Audit 20 Process Verification To Management Viamed 24 Aug 2016 Process: 7723

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.

Records - Control, Creation, Storage, Retrieval and Revision control

Revision Document
 ID30999

Date Revision 30 Sep 2019

Reviewed 30 Sep 2019

Explanation Quality Objectives

Revision Document
 ID18483

Date Revision 18 Jan 2017

Reviewed 18 Jan 2017

VM3COP00.00 VST

Quality Statement policy and objectives

Revision Document
 ID22062

Date Revision 16 Sep 2017

Reviewed 24 Aug 2020

Explanation Employee

Roles and Titles

Revision Document
 ID22144

Date Revision 20 Sep 2017

Reviewed 20 Sep 2017

Audit 20 Process verification to Management

Revision Document
 ID41418

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Audit 10 Documentation Control

Revision Document
 ID42704

Date Revision 01 Sep 2020

Reviewed 01 Sep 2020

VM3COP00.01 Company objectives

Revision Document
 ID22842

Date Revision 17 Oct 2017

Reviewed 17 Oct 2017

Audit 10b Process Verification Viamed 24 Aug 2016

Process: 7834

Financial Review 20 Sep 2017

Process: 7862

Review The Audit Calender Screen 04 Oct 2017

Process: 27

Management Reviews And Quality Audits 16 Feb 2016

Process: 5877

Review Company Data 17 Feb 2016

Process: 6861

Management Meeting Review Weekly Meeting 09 Mar 2016

Process: 7037

Responsibility Allocation : Responsibility, authority and communication 09 Mar 2016

Process: 7057

Responsibility Allocation : Complaints and Vigilance Notifications 09 Mar 2016

Process: 7070

Management Review 09 Mar 2016

Process: 7713

Review Roles And Responsibilitys 17 Aug 2016

Process: 7830

Review Q.A. Failures Report 18 Sep 2017

Process: 7837

Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017

Process: 7838

Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017

Process: 7839

Review VIAMED Feedback - Customer Complaints 23 Sep 2017

Process: 7842

Review VIAMED Product Feedback Negative 23 Sep 2017

Process: 7845

7.1.4 Environment Of Operations 25 Sep 2017

Process: 7848

Review ISO Scopes 27 Sep 2017

Process: 7849

Review Product Failures New Codes 28 Sep 2017

Process: 7120

General Maintenance Requirements 09 Mar 2016

Process: 28

Supplier Review 16 Feb 2016

Process: 5887

Review ISO/EN Documents 24 Feb 2016

Process: 5889

Responsibility Allocation : Audit And Task - Audit 24 Feb 2016

Process: 6866

		Internal Process Verification Complete Systems Review 09 Mar 2016 Process: 7199 Non Conformities Review 09 Mar 2016 Process: 7828 Review The Quality Policy Viamed 16 Sep 2017 Process: 6821 Responsibility Allocation : VIAMED Management Meeting Supplier Review 09 Mar 2016 Process: 7697 Yearly Pricing Review 09 May 2016 Process: 57 Temporary Stock Notices 17 Feb 2016
4.2.2 Quality manual The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO Revision Document ID41667 Date Revision 11 Aug 2020 Reviewed 11 Aug 2020 Top Level Document: VM3COP02.02 Viamed Company Responsibility's organisation chart structure Revision Document ID27474 Date Revision 20 Sep 2018 Reviewed 20 Sep 2018 Top Level Document: Viamed ISO 13485:2016 Scope Revision Document ID31634 Date Revision 14 Nov 2019 Reviewed 28 Sep 2020 Structure of the documentation used in the quality management system Revision Document ID18487 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 10 Documentation Control Revision Document ID42704	Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016

	Date Revision 01 Sep 2020 Reviewed 01 Sep 2020	
4.2.3 Medical device file For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity with the requirement of this International Standard and compliance with applicable regulatory requirements. The content of the file(s) shall include, but is not limited to: a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use; b) specifications for product; c) specifications or procedures for manufacturing, packaging, storage, handling and distribution; d) procedures for measuring and monitoring; e) as appropriate, requirements for installation; f) as appropriate, procedures for servicing.	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Route to Medical device files Revision Document ID18495 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016
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;	Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control Revision Document ID30999 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Explanation Control of documents Revision Document ID21322 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 DO NOT USE VM3COP01 Document Updates / Amendment control Revision Document ID22201	Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016

d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled; g) prevent deterioration or loss of documents; h) prevent the unintended use of obsolete documents and apply suitable identification to them. The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to 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	Date Revision 23 Sep 2017 Reviewed 23 Sep 2017 Audit 10 Documentation Control Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020 DO NOT USE VM3COP14 Documentation Revision Document ID9276 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	
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	Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control Revision Document ID30999 Date Revision 30 Sep 2019	Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016

define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

Reviewed 30 Sep 2019
DO NOT USE VM3COP01
Document Updates /
Amendment control
Revision Document
ID22201
Date Revision 23 Sep 2017
Reviewed 23 Sep 2017
VM3COP14.01 Disposition
of Documents / Records.
Revision Document
ID15464
Date Revision 14 Aug 2015
Reviewed 14 Aug 2015
Guide to Intrastats
Revision Document
ID24779
Date Revision 22 Dec 2017
Reviewed 22 Dec 2017
Intrastats overview
Revision Document
ID23567
Date Revision 28 Oct 2017
Reviewed 28 Oct 2017
DO NOT USE VM3COP14
Documentation
Revision Document ID9276
Date Revision 18 Oct 2011
Reviewed 18 Oct 2011
Audit 10 Documentation
Control
Revision Document
ID42704
Date Revision 01 Sep 2020
Reviewed 01 Sep 2020

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	Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure Revision Document ID31036 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VM3COP00.00 Viamed Quality Statement policy	Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016 Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016 Process: 7833 Importance Of Effective Quality Management 20 Sep 2017 Process: 27 Management Reviews And Quality Audits 16 Feb 2016 Process: 7070 Management Review 09 Mar 2016 Process: 7848 Review ISO Scopes 27 Sep 2017 Process: 23 Company Objectives 16 Feb 2016
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reviews;
e) ensuring the availability
of resources. **Management
commitment**

and objectives

Revision Document

ID22684

Date Revision 16 Oct 2017

Reviewed 22 Sep 2020

VM3COP02 Organisation

Responsibilities Viamed

Revision Document

ID17423

Date Revision 07 Sep 2016

Reviewed 07 Sep 2016

Chart 01 System and

Documentation

Revision Document ID8675

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

Chart 02 Resource

Management

Revision Document ID8676

Date Revision 12 Oct 2011

Reviewed 12 Oct 2011

VM3COP19 Health and

Safety

Revision Document

ID21800

Date Revision 05 Sep 2017

Reviewed 05 Sep 2017

Audit 20 Process

verification to Managment

Revision Document

ID41418

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Explanation Quality

Objectives

Revision Document

ID18483

Date Revision 18 Jan 2017

Reviewed 18 Jan 2017

Explanation Employee

Roles and Titles

Revision Document

ID22144

Date Revision 20 Sep 2017

Reviewed 20 Sep 2017

Explanation Control of

documents

Revision Document

ID21322

Date Revision 06 Aug 2017

Reviewed 06 Aug 2017

How to Hold Intrastat

Meetings

Revision Document ID8928

Date Revision 18 Oct 2011

Reviewed 18 Oct 2011

Chart 40 Management

review plan Issues

	followup Revision Document ID22458 Date Revision 05 Oct 2017 Reviewed 05 Oct 2017 Audit 18 Management Review Revision Document ID41388 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Viamed Top Level Quality Objectives Revision Document ID22429 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 Contract Review, Enquires, Office Processes Revision Document ID33748 Date Revision 18 Mar 2020 Reviewed 18 Mar 2020 Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd Revision Document ID31040 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Revision Document ID31076 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 02 Contract Review and Sales Order Processing Revision Document ID33205 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 Audit 16 Sales and Marketing Revision Document ID41236 Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	Process: 7 Responsibility Allocation : Checking Of Sales Orders 16 Feb 2016 Process: 11 Distribution Of Mail 16 Feb 2016 Process: 5882 Responsibility Allocation : Send Post To Humanmed 24 Feb 2016 Process: 2 Answering Telephones 16 Feb 2016 Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016 Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016
5.3 Top management shall ensure that the quality	Top Level Document: VM3COP00.00 Viamed Quality Statement policy	Process: 23 Company Objectives 16 Feb 2016 Process: 22

policy: a) is applicable to the purpose of the organization; b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; c) provides a framework for establishing and reviewing quality objectives; d) is communicated and understood within the organization; e) is reviewed for continuing suitability. Quality policy	and objectives Revision Document ID22684 Date Revision 16 Oct 2017 Reviewed 22 Sep 2020 VM3COP00.00 VST Quality Statement policy and objectives Revision Document ID22062 Date Revision 16 Sep 2017 Reviewed 24 Aug 2020 VM3COP00.01 Company objectives Revision Document ID22842 Date Revision 17 Oct 2017 Reviewed 17 Oct 2017 Audit 18 Management Review Revision Document ID41388 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	Company Policys 16 Feb 2016 Process: 23 Company Objectives 16 Feb 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7833 Importance Of Effective Quality Management 20 Sep 2017 Process: 7828 Review The Quality Policy Viamed 16 Sep 2017 Process: 7827 Review The Quality Policy VST 16 Sep 2017
5.4 Planning		
5.4.1 Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Quality objectives	Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Revision Document ID31076 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 VM3COP18 Post Market Surveillance Revision Document ID8106 Date Revision 21 Mar 2011 Reviewed 21 Mar 2011 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 Explanation Quality Objectives Revision Document ID18483 Date Revision 18 Jan 2017	Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016 Process: 7830 Review Q.A. Failures Report 18 Sep 2017 Process: 26 Company Resources 16 Feb 2016 Process: 5877 Review Company Data 17 Feb 2016

	Reviewed 18 Jan 2017 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Viamed Top Level Quality Objectives Revision Document ID22429 Date Revision 04 Oct 2017 Reviewed 04 Oct 2017	
5.4.2 Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. Quality management system planning	Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure Revision Document ID27474 Date Revision 20 Sep 2018 Reviewed 20 Sep 2018 Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives Revision Document ID22684 Date Revision 16 Oct 2017 Reviewed 22 Sep 2020 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 Explanation Quality Objectives Revision Document ID18483 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 Explanation Control of documents Revision Document ID21322 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 Route to Medical device files Revision Document ID18495 Date Revision 18 Jan 2017 Reviewed 18 Jan 2017 VM3COP20.01 Post In Distributing the Post Revision Document	Process: 11 Distribution Of Mail 16 Feb 2016 Process: 5882 Responsibility Allocation : Send Post To Humanmed 24 Feb 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016

	ID18641 Date Revision 10 Feb 2017 Reviewed 10 Feb 2017 VM3COP00.00 VST Quality Statement policy and objectives Revision Document ID22062 Date Revision 16 Sep 2017 Reviewed 24 Aug 2020 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Viamed Top Level Quality Objectives Revision Document ID22429 Date Revision 04 Oct 2017 Reviewed 04 Oct 2017 VM3COP00.01 Company objectives Revision Document ID22842 Date Revision 17 Oct 2017 Reviewed 17 Oct 2017	
5.5 Responsibility, authority and communication	Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019	
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 ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure Revision Document ID27474 Date Revision 20 Sep 2018 Reviewed 20 Sep 2018 Explanation Employee Roles and Titles	Process: 7720 Audit 08 Training Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016 Process: 7713 Review Roles And Responsibilitys 17 Aug 2016 Process: 6837 Personnel Requirements and Training 09 Mar 2016

Revision Document
ID22144
Date Revision 20 Sep 2017
Reviewed 20 Sep 2017
**VM3COP02 Organisation
Responsibilities Viamed**
Revision Document
ID17423
Date Revision 07 Sep 2016
Reviewed 07 Sep 2016
**Chart 01 System and
Documentation**
Revision Document ID8675
Date Revision 12 Oct 2011
Reviewed 12 Oct 2011
**Chart 02 Resource
Management**
Revision Document ID8676
Date Revision 12 Oct 2011
Reviewed 12 Oct 2011
**Viamed Company Format
Company format 1**
Revision Document ID9039
Date Revision 18 Oct 2011
Reviewed 18 Oct 2011
**Viamed Company Format
Company format 2**
Revision Document ID9040
Date Revision 18 Oct 2011
Reviewed 18 Oct 2011
**Viamed Company Format
Company format 3**
Revision Document ID9041
Date Revision 18 Oct 2011
Reviewed 18 Oct 2011
**Viamed Company Format
Company format 4**
Revision Document ID9042
Date Revision 18 Oct 2011
Reviewed 18 Oct 2011
**Audit 08 Training,
Competence and Human
Resources**
Revision Document
ID40199
Date Revision 13 Jul 2020
Reviewed 13 Jul 2020
**Audit 20 Process
verification to Managment**
Revision Document
ID41418
Date Revision 06 Aug 2020
Reviewed 06 Aug 2020
**Audit 19 Health and
Safety, Working
Conditions and Building
Fabric Issues**
Revision Document

	ID41398 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	
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	Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure Revision Document ID27474 Date Revision 20 Sep 2018 Reviewed 20 Sep 2018 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 VM3COP02 Organisation Responsibilitys Viamed Revision Document ID17423 Date Revision 07 Sep 2016 Reviewed 07 Sep 2016 VM3COP02 Organisation VST Revision Document ID13954 Date Revision 19 May 2014 Reviewed 19 May 2014 VM3COP02.02 VST Company Responsibilitys organisation chart structure Revision Document ID29373 Date Revision 23 Apr 2019 Reviewed 23 Apr 2019	Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016 Process: 7833 Importance Of Effective Quality Management 20 Sep 2017
5.5.3 Top management shall ensure that appropriate communication processes	VM3COP27.01 Searching Intrastats Issues Revision Document ID6657 Date Revision 02 Nov 2009	

are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Internal communication

Reviewed 02 Nov 2009

Intrastats overview

Revision Document

ID23567

Date Revision 28 Oct 2017

Reviewed 28 Oct 2017

Issues Overview

Revision Document

ID23112

Date Revision 22 Oct 2017

Reviewed 22 Oct 2017

Overview Issues Meeting

Headers List

Revision Document

ID22169

Date Revision 22 Sep 2017

Reviewed 22 Sep 2017

Chart 42 Processes, Tasks and Audits Review

Revision Document

ID23559

Date Revision 28 Oct 2017

Reviewed 28 Oct 2017

Chart 43 Processes and Intrastats

Revision Document

ID23561

Date Revision 28 Oct 2017

Reviewed 28 Oct 2017

Chart 37 New Processes

Revision Document

ID23563

Date Revision 28 Oct 2017

Reviewed 28 Oct 2017

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

Top Level Document: VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data

Revision Document

ID53797

Date Revision 16 Feb 2021

Reviewed 16 Feb 2021

How to Hold Intrastat Meetings

Revision Document ID8928

Date Revision 18 Oct 2011

Reviewed 18 Oct 2011

Audit 18 Management Review

Revision Document

ID41388

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Audit 10 Documentation Control

Process: 7846

ISO System Management Review 26 Sep 2017

Process: 27

Management Reviews And Quality Audits 16 Feb 2016

Process: 7070

Management Review 09 Mar 2016

	Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020 Management Review Revision Document ID30851 Date Revision 18 Sep 2019 Reviewed 18 Sep 2019 Management reviews Revision Document ID19801 Date Revision 05 May 2017 Reviewed 05 May 2017	
5.6.2 Review input The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.	Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd Revision Document ID31040 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd Revision Document ID31052 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VM3COP02.02 Viamed Company Responsibility organisation chart structure Revision Document ID27474 Date Revision 20 Sep 2018 Reviewed 20 Sep 2018 Top Level Document: VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data Revision Document ID53797 Date Revision 16 Feb 2021 Reviewed 16 Feb 2021 Chart 27 Customer Complaints Chart 27 Revision Document ID8700 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 VM3COP18 Post Market Surveillance Revision Document ID8106 Date Revision 21 Mar 2011	Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7838 Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 Process: 7839 Review VIAMED Feedback - Customer Complaints 23 Sep 2017 Process: 7842 Review VIAMED Product Feedback Negative 23 Sep 2017 Process: 7846 ISO System Management Review 26 Sep 2017 Process: 7848 Review ISO Scopes 27 Sep 2017 Process: 7849 Review Product Failures New Codes 28 Sep 2017 Process: 7871 Review Exclusion From Viamed 13485:2016 And VST 9001:2015 15 Oct 2017 Process: 7837 Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 Process: 7830 Review Q.A. Failures Report 18 Sep 2017 Process: 7741 Review Ethical Policy 14 Sep 2016 Process: 7713 Review Roles And Responsibilitys 17 Aug 2016 Process: 7070 Management Review 09 Mar 2016 Process: 6931 Customer Complaints 09 Mar 2016 Process: 7091 Calibration Index 09 Mar 2016

	Reviewed 21 Mar 2011 How to Hold Intrastat Meetings Revision Document ID8928 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 Audit 18 Management Review Revision Document ID41388 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 21 Audit of Audit Revision Document ID41422 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 22 Post Market Surveillance Revision Document ID41428 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Management Review Blank Minutes 20xx Revision Document ID45125 Date Revision 06 Oct 2020 Reviewed 06 Oct 2020	
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 ID23112 Date Revision 22 Oct 2017 Reviewed 22 Oct 2017 VM3COP27.01 Searching Intrastats Issues Revision Document ID6657 Date Revision 02 Nov 2009 Reviewed 02 Nov 2009 Management Review Revision Document ID30851 Date Revision 18 Sep 2019 Reviewed 18 Sep 2019 Management reviews Revision Document ID19801 Date Revision 05 May 2017 Reviewed 05 May 2017 Management reviews minutes Revision Document	Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016

	ID19803 Date Revision 05 May 2017 Reviewed 05 May 2017 Audit 20 Process verification to Management Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 18 Management Review Revision Document ID41388 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	
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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	Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 20 Process verification to Management Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Management Viamed 24 Aug 2016
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 or take other actions to achieve or maintain the necessary	Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 12 Training Revision Document ID31024 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017	Process: 7720 Audit 08 Training Viamed 24 Aug 2016

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. Human resources	Audit 08 Training, Competence and Human Resources Revision Document ID40199 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020 Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Revision Document ID41398 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	
6.3 The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such	Top Level Document: VOP 16 Health and Safety, Company Personnel Manual Revision Document ID31032 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure Revision Document ID31036 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 06 Measurement Control Viamed VST, Calibration, QA Stock Revision Document ID53615 Date Revision 11 Feb 2021 Reviewed 11 Feb 2021 Top Level Document: VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment Revision Document ID31008 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 DO NOT USE VM3COP11 Calibration Revision Document ID8713 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011	Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016 Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 Process: 6855 Risk Assessment HSE 09 Mar 2016 Process: 6856 Fire Alarms 09 Mar 2016 Process: 54 Responsibility Allocation : Gents Toilets 17 Feb 2016 Process: 5907 Hoover Warehouse 03 Mar 2016 Process: 5908 Sweep Warehouse 03 Mar 2016 Process: 5909 Empty Warehouse Bins 03 Mar 2016 Process: 5911 Clear Cardboard 03 Mar 2016 Process: 5856 Cleaning The Kitchen 17 Feb 2016 Process: 7802 Clean Kitchen Sides 22 May 2017 Process: 7803 Dishwashing 22 May 2017 Process: 7804 Sweep Kitchen Floor 22 May 2017 Process: 7805 Empty Kitchen Bins 22 May 2017 Process: 7806 Watering Plants 22 May 2017 Process: 56 Warehouse Outside Heating Guard 17 Feb 2016

maintenance shall be
maintained **Infrastructure**

HSE Fire appliances HSE
Fire Exit / Escape Route
Ground Floor plans
Revision Document
ID27944
Date Revision 29 Oct 2018
Reviewed 29 Oct 2018
HSE Fire Exit / Escape
Route Ground Floor plans
Document
Revision Document ID2558
Date Revision 01 Aug 2007
Reviewed 01 Aug 2007
HSE Fire Risk Assessment
Revision Document
ID21790
Date Revision 04 Sep 2017
Reviewed 04 Sep 2017
HSE Fire Safety Risk
Assessment
Revision Document ID892
Date Revision 25 Oct 2006
Reviewed 25 Oct 2006
HSE Fire / Exit Escape
route Basement floor plans
Revision Document
ID15401
Date Revision 07 Aug 2015
Reviewed 28 Sep 2020
HSE Fire / Exit Escape
route Ghyll House floor
plans
Revision Document
ID27948
Date Revision 29 Oct 2018
Reviewed 29 Oct 2018
Ghyll House Fire
Certificate
Revision Document
ID12303
Date Revision 15 Mar 2013
Reviewed 15 Mar 2013
CPM 21 Fire Exit / Escape
Route Procedures
Revision Document
ID21892
Date Revision 07 Sep 2017
Reviewed 07 Sep 2017
FIRE Report Premisis
Revision Document
ID61402
****Date Revision 02 Jun**
2021 Reviewed 02 Jun 2021
VM3COP20.35 Ups
Calculator
Revision Document
ID17149
Date Revision 05 Jul 2016

Process: 5919
Check Out Side Drain 05 Mar 2016
Process: 5921
Clearing Water Downstairs 05 Mar 2016
Process: 7120
General Maintenance Requirements 09 Mar 2016
Process: 7742
Boiler Check 26 Sep 2016
Process: 7756
Carbon Monoxide Alarm 05 Jan 2017
Process: 7820
North Yorkshire Council Waste Tranfer 15 Jun 2017
Process: 7821
Controlled Waste Description And Transfer 15 Jun 2017
Process: 7835
Electrics Need Checking 20 Sep 2017
Process: 7836
Central Heating For Winter 20 Sep 2017
Process: 7713
Review Roles And Responsibilitys 17 Aug 2016
Process: 7845
7.1.4 Environment Of Operations 25 Sep 2017
Process: 45
Responsibility Allocation : Main Server Status 16 Feb 2016
Process: 48
Responsibility Allocation : Internet 16 Feb 2016
Process: 52
Software Verification Clear Down Backup Emails 16 Feb 2016
Process: 5903
Responsibility Allocation : Weather Station 02 Mar 2016
Process: 5939
Responsibility Allocation : Email ISP Routing 05 Mar 2016
Process: 7121
Responsibility Allocation : General Computer Maintenance 09 Mar 2016
Process: 7129
Intrastats Cross Reference Database Tables Updates 09 Mar 2016
Process: 7672
Off Site Backup 09 Mar 2016
Process: 7704
Responsibility Allocation : Computer Failure Diagnostics 24 May 2016
Process: 7850
Software Validation Scan In Correct Product 01 Oct 2017
Process: 7851
Software Validation Scan Un-QA Product To Order 01 Oct 2017

	Reviewed 05 Jul 2016 VM3COP20.07 UPS Procedures Revision Document ID8722 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 VM3COP03.05 Procedures for customer returning goods on our UPS account number Revision Document ID17155 Date Revision 05 Jul 2016 Reviewed 05 Jul 2016 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Revision Document ID41398 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 15 Production Revision Document ID59614 Date Revision 11 May 2021 Reviewed 11 May 2021	Process: 7852 Software Validation Expired Stock 01 Oct 2017 Process: 7853 Software Validation Non Sell Able Shelf 01 Oct 2017 Process: 7854 Software Validation In Production List 01 Oct 2017 Process: 7855 Software Validation - Production Lists 01 Oct 2017 Process: 7856 Software Validation Unchecked Orders 01 Oct 2017 Process: 7857 Software Validation Stock Tracking Check 01 Oct 2017 Process: 7858 Software Validation Attempt To QA Some Stock 01 Oct 2017 Process: 7861 Software Validation Of Training Documents Forced Reading 03 Oct 2017
6.4 Work environment and contamination control Work environment and contamination control		
6.4.1 The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the	Top Level Document: VOP 16 Health and Safety, Company Personnel Manual Revision Document ID31032 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure Revision Document ID31036 Date Revision 30 Sep 2019	Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016 Process: 7720 Audit 08 Training Viamed 24 Aug 2016 Process: 7729 Audit 19 Health And Safety Viamed 24 Aug 2016 Process: 56 Warehouse Outside Heating Guard 17 Feb 2016 Process: 5919 Check Out Side Drain 05 Mar 2016 Process: 5921

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	Reviewed 30 Sep 2019 CPM 15 Disciplinary Procedures Revision Document ID25502 Date Revision 05 Mar 2018 Reviewed 05 Mar 2018 CPM 16 Dress Code Revision Document ID7055 Date Revision 26 Apr 2010 Reviewed 22 Jul 2014 CPM 25 Health and Safety Policy Viamed Revision Document ID14332 Date Revision 25 Sep 2014 Reviewed 04 Sep 2017 CPM 39 Smoking Policy Revision Document ID6782 Date Revision 15 Feb 2010 Reviewed 15 Feb 2010 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 08 Training, Competence and Human Resources Revision Document ID40199 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020 Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Revision Document ID41398 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020	Clearing Water Downstairs 05 Mar 2016 Process: 7120 General Maintenance Requirements 09 Mar 2016 Process: 7742 Boiler Check 26 Sep 2016 Process: 7756 Carbon Monoxide Alarm 05 Jan 2017 Process: 7820 North Yorkshire Council Waste Transfer 15 Jun 2017 Process: 7821 Controlled Waste Description And Transfer 15 Jun 2017 Process: 7835 Electrics Need Checking 20 Sep 2017 Process: 7836 Central Heating For Winter 20 Sep 2017 Process: 7864 ESD Work Stations 07 Oct 2017 Process: 7873 On Site Environment Review 18 Oct 2017 Process: 54 Responsibility Allocation : Gents Toilets 17 Feb 2016 Process: 5906 Empty Paper Bins 03 Mar 2016 Process: 5907 Hoover Warehouse 03 Mar 2016 Process: 5908 Sweep Warehouse 03 Mar 2016 Process: 5909 Empty Warehouse Bins 03 Mar 2016 Process: 5910 Clean Duckets 03 Mar 2016 Process: 5911 Clear Cardboard 03 Mar 2016 Process: 7698 Clean Toilets 17 May 2016
6.4.2 As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or	Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO Revision Document ID41667 Date Revision 11 Aug 2020 Reviewed 11 Aug 2020 Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection Revision Document ID31044 Date Revision 30 Sep 2019	Process: 39 Environmental Policy Document Review 16 Feb 2016 Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016 Process: 7714 Audit 01 Picking Packing Viamed 24 Aug 2016 Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016

particulate matter and maintain the required cleanliness during assembly or packaging processes.
Contamination control

Reviewed 30 Sep 2019
Top Level Document: VOP 09 Repairs and Servicing
Revision Document
ID31020
Date Revision 30 Sep 2019
Reviewed 30 Sep 2019

7 Product realization

7 Product realization

7.1
The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5).

In planning product realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish 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

Top Level Document: VOP 08 Production, Reworks, New Production
Revision Document
ID31072
Date Revision 30 Sep 2019
Reviewed 30 Sep 2019
Top Level Document: VM3COP27.11 Performing a Technical File PMS and risk assessment
Revision Document
ID17824
Date Revision 03 Nov 2016
Reviewed 25 Jan 2021
VM3COP24.00 Viamed Overall Risk Analysis Program
Revision Document
ID47771
Date Revision 12 Nov 2020
Reviewed 12 Nov 2020
VM3COP27.12 Clinical Evaluation Risk assessment Technical Files
Revision Document
ID15453
Date Revision 11 Aug 2015
Reviewed 11 Aug 2015
Audit 22 Post Market Surveillance
Revision Document
ID41428
Date Revision 06 Aug 2020
Reviewed 06 Aug 2020
Audit 03 Design Control
Revision Document
ID51631
Date Revision 13 Jan 2021
Reviewed 13 Jan 2021
Audit 07 Handling and Storage
Revision Document
ID58347

Process: 7732
Audit 22 Post Market Surveillance Viamed 24 Aug 2016
Process: 7716
Audit 03 Design Control Viamed 24 Aug 2016

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	Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Audit 09 Goods Inward and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021 Reviewed 12 Mar 2021 Audit 10 Documentation Control Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020	
7.2 Customer-related processes		
7.2.1 The organization shall determine: a) requirements specified by the customer, including the requirements for delivery and postdelivery activities; b) requirements not stated by the customer but necessary for specified or intended use, as known; c) applicable regulatory requirements related to the product; d) any user training needed to ensure specified performance and safe use of the medical device; e) any additional requirements determined by the organization Determination of requirements related to product	Top Level Document: VOP 03 Contract Review, Enquires, Office Processes Revision Document ID33748 Date Revision 18 Mar 2020 Reviewed 18 Mar 2020 Audit 22 Post Market Surveillance Revision Document ID41428 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 02 Contract Review and Sales Order Processing Revision Document ID33205 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 VM3COP20.31 Export Order Processing Revision Document ID22016 Date Revision 15 Sep 2017 Reviewed 15 Sep 2017 VM3COP03.01 Order Processing Priorities Revision Document ID20049 Date Revision 15 May 2017 Reviewed 15 May 2017 VM3COP20.30 UK Order Processing Revision Document	Process: 7732 Audit 22 Post Market Surveillance Viamed 24 Aug 2016 Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017 Process: 5 Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017 Process: 7 Responsibility Allocation : Checking Of Sales Orders 16 Feb 2016 Process: 7734 Responsibility Allocation : Humanmed Order Processing 25 Aug 2016 Process: 5 Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016 Process: 7734 Responsibility Allocation : Humanmed Order Processing 25 Aug 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017

ID47862
Date Revision 13 Nov 2020
Reviewed 13 Nov 2020
VM3COP03.07
Humanmed Order
Checking
Revision Document
ID22266
Date Revision 27 Sep 2017
Reviewed 27 Sep 2017
VM3COP03.08
Humanmed Order
Processing
Revision Document
ID24775
Date Revision 22 Dec 2017
Reviewed 22 Dec 2017
VM3COP20.32 Order
Checking
Revision Document
ID34889
Date Revision 01 Apr 2020
Reviewed 01 Apr 2020
Infant Resuscitation
Cabinet - Training
Assessment Form
Revision Document
ID14334
Date Revision 25 Sep 2014
Reviewed 25 Sep 2014
Oxygen Sensor Training
Powerpoint
Revision Document
ID15736
Date Revision 24 Sep 2015
Reviewed 25 Oct 2016
Oxygen Sensor Training
Video
Revision Document
ID15737
Date Revision 24 Sep 2015
Reviewed 24 Sep 2015
Resuscitation Unit and
TC400 Training
Information Resuscitation
Cabinet Training
Revision Document ID4111
Date Revision 09 Jul 2008
Reviewed 09 Jul 2008
Resuscitation Unit
Maintenance Therapy
Equipment Suction
Controller Unit and TC400
Training Information
Therapy Workshop Inst.
Revision Document ID4122
Date Revision 09 Jul 2008
Reviewed 09 Jul 2008

**Single Use Surgical
Training Information
certificates**

Revision Document
ID20220

Date Revision 19 May 2017
Reviewed 19 May 2017

**SpO2 800 series Training
Information**

Revision Document
ID12687

Date Revision 02 Jul 2013
Reviewed 02 Jul 2013

**TECcare Training
Material**

Revision Document
ID11826

Date Revision 11 Jun 2012
Reviewed 11 Jun 2012

**Temperature Probe
Training Material**

Revision Document
ID18169

Date Revision 05 Dec 2016
Reviewed 05 Dec 2016

**Tom Thumb Training
Information**

Revision Document ID7880

Date Revision 07 Mar 2011
Reviewed 07 Mar 2011

**Tom Thumb Training
Information 2009**

Revision Document
ID15644

Date Revision 16 Sep 2015
Reviewed 16 Sep 2015

**Tom Thumb Training
Information Training
Manual Training
Information**

Revision Document ID2973

Date Revision 31 Jan 2008
Reviewed 31 Jan 2008

**Tom Thumb Training
Information Training V1.1**

Revision Document
ID15641

Date Revision 16 Sep 2015
Reviewed 16 Sep 2015

**Training information
Infant Resuscitation Unit**

Revision Document ID8665

Date Revision 12 Oct 2011
Reviewed 12 Oct 2011

**VM-2500 Product Training
Materials - Frequently
Asked Questions**

Revision Document ID6967

	Date Revision 17 Mar 2010 Reviewed 17 Mar 2010 VM-2500 Product Training Materials Capnography Product Application Notes Revision Document ID6749 Date Revision 08 Feb 2010 Reviewed 08 Feb 2010 VM-2500 Product Training Materials Capnography Product Presentation MASTER Revision Document ID6750 Date Revision 08 Feb 2010 Reviewed 08 Feb 2010 VM-2500 Product Training Materials Mainstream or Sidestream Capnography Revision Document ID6753 Date Revision 08 Feb 2010 Reviewed 08 Feb 2010 VM3COP12.01 Viamed Policy on End User Training UK Revision Document ID23571 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Audit 01 Picking packing Revision Document ID51629 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 16 Sales and Marketing Revision Document ID41236 Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	
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 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	Top Level Document: VOP 03 Contract Review, Enquires, Office Processes Revision Document ID33748 Date Revision 18 Mar 2020 Reviewed 18 Mar 2020 Audit 02 Contract Review and Sales Order Processing Revision Document ID33205 Date Revision 08 Mar 2020 Reviewed 08 Mar 2020 Audit 11 Repairs, Servicing and Returns Revision Document ID41150	Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016 Process: 7724 Audit 11 Repairs And Service Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016

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	Date Revision 02 Aug 2020 Reviewed 02 Aug 2020 Audit 20 Process verification to Management Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 10 Documentation Control Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020	
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 Contract Review, Enquires, Office Processes Revision Document ID33748 Date Revision 18 Mar 2020 Reviewed 18 Mar 2020 Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd Revision Document ID31040 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 VM3COP27.31 Processing Proforma Invoices and Quotations Revision Document ID26885 Date Revision 31 Jul 2018 Reviewed 31 Jul 2018 VM3COP20.05 New Orders - How to enter into Opera Viamed Revision Document ID13695	Process: 2 Answering Telephones 16 Feb 2016 Process: 7710 Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017 Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7726 Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016

Date Revision 12 May 2014

Reviewed 12 May 2014

VM3COP20.32 Order

Checking

Revision Document

ID34889

Date Revision 01 Apr 2020

Reviewed 01 Apr 2020

VM3COP20.49 Informing

Customers of Price

Amends

Revision Document

ID18357

Date Revision 05 Jan 2017

Reviewed 05 Jan 2017

VM3COP20.031 Viamed

Repair Procedures

Invoicing / customer

paperwork

Revision Document

ID24753

Date Revision 21 Dec 2017

Reviewed 21 Dec 2017

VM3COP20.22 Quoting

Customer Special prices.

Revision Document

ID15613

Date Revision 09 Sep 2015

Reviewed 09 Sep 2015

VM3COP10.02 Product

**Recall locate products out
in the Field**

Revision Document

ID23643

Date Revision 28 Oct 2017

Reviewed 28 Oct 2017

Audit 14 Complaints and

Corrective Actions

Revision Document

ID41228

Date Revision 03 Aug 2020

Reviewed 03 Aug 2020

**Audit 02 Contract Review
and Sales Order**

Processing

Revision Document

ID33205

Date Revision 08 Mar 2020

Reviewed 08 Mar 2020

Audit 16 Sales and

Marketing

Revision Document

ID41236

Date Revision 03 Aug 2020

Reviewed 03 Aug 2020

Audit 22 Post Market

Survellance

Revision Document

	ID41428 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 01 Picking packing Revision Document ID51629 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 04 Accounts and Finance Revision Document ID61390 **Date Revision 02 Jun 2021 Reviewed 02 Jun 2021	
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 ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 BSI Technical File Design File Requirements Dossier Revision Document ID4959 Date Revision 29 Dec 2008 Reviewed 29 Dec 2008 CE & Design files re-organisation Revision Document ID9085 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 Chart 04 Design and Development Revision Document ID8678 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 Chart 17 Design Repairs Revision Document ID8690 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 Chart 30 System Design Plan Revision Document ID8703 Date Revision 12 Oct 2011	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016

	Reviewed 12 Oct 2011 New Project Design File Content Revision Document ID9093 Date Revision 18 Oct 2011 Reviewed 18 Oct 2011 VM3COP16 Design and Design Changes Design requirements Revision Document ID7396 Date Revision 10 Jan 2011 Reviewed 10 Jan 2011 Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	
7.3.2 The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development; e) the methods to ensure traceability of design and development outputs to design and development inputs; f) the resources needed including necessary competence of personnel Design and development planning	Top Level Document: VM3COP27.11 Performing a Technical File PMS and risk assessment Revision Document ID17824 Date Revision 03 Nov 2016 Reviewed 25 Jan 2021 Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID31096 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 VM3COP16 Design and Design Changes Design requirements Revision Document ID7396 Date Revision 10 Jan 2011 Reviewed 10 Jan 2011 VM3COP27.07 Project Manager Revision Document ID12734 Date Revision 11 Jul 2013 Reviewed 11 Jul 2013 VM3COP27.12 Clinical Evaluation Risk assessment Technical Files Revision Document	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7720 Audit 08 Training Viamed 24 Aug 2016

	ID15453 Date Revision 11 Aug 2015 Reviewed 11 Aug 2015 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 08 Training, Competence and Human Resources Revision Document ID40199 Date Revision 13 Jul 2020 Reviewed 13 Jul 2020 Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 QC 28B Design Changes Revision Document ID25508 Date Revision 05 Mar 2018 Reviewed 05 Mar 2018 Generic CE File Attached to All Assignment of responsibility Risk Management Revision Document ID7742 Date Revision 02 Mar 2011 Reviewed 02 Mar 2011	
7.3.3 Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include: a) functional, performance, usability and safety requirements, according to the intended use; b) applicable regulatory requirements and standards; c) applicable output(s) of risk management; d) as appropriate, information derived from previous similar designs; e) other requirements	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 12 CE Files	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016

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	Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	
7.3.4 Design and development outputs shall: a) meet the input requirements for design and development; b) provide appropriate information for purchasing, production and service provision; c) contain or reference product acceptance criteria; d) specify the characteristics of the product that are essential for its safe and proper use. The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release. Records of the design and development outputs shall be maintained (see 4.2.5). Design and development outputs	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016
7.3.5 Design and development review	Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	
7.3.5 At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016

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).	Reviewed 19 Mar 2018 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	
7.3.6 Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements. The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5). Design	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Top Level Document: VOP 15 Data and Information Analysis Revision Document ID31056 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	

and development verification		
7.3.7 Design and development validation	Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 QC 30b Project Verification & Validation Summary Master Revision Document ID25482 Date Revision 01 Mar 2018 Reviewed 01 Mar 2018	
7.3.7 Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. The organization shall document validation plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size. Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5). As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Top Level Document: VOP 15 Data and Information Analysis Revision Document ID31056 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016

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	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 <i>Date Revision 19 Mar 2018</i> <i>Reviewed 19 Mar 2018</i> Audit 03 Design Control Revision Document ID51631 <i>Date Revision 13 Jan 2021</i> <i>Reviewed 13 Jan 2021</i> Audit 12 CE Files Revision Document ID58351 <i>Date Revision 23 Apr 2021</i> <i>Reviewed 23 Apr 2021</i>	Process: 7716 <i>Audit 03 Design Control Viamed 24 Aug 2016</i> Process: 7722 <i>Audit 10 Documentation Control Viamed 24 Aug 2016</i>
7.3.9 The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified. Before implementation, the changes shall be: a) reviewed;	Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 <i>Date Revision 19 Mar 2018</i> <i>Reviewed 19 Mar 2018</i> Audit 03 Design Control Revision Document ID51631 <i>Date Revision 13 Jan 2021</i> <i>Reviewed 13 Jan 2021</i> Audit 12 CE Files Revision Document ID58351 <i>Date Revision 23 Apr 2021</i> <i>Reviewed 23 Apr 2021</i> QC 28B Design Changes	Process: 7716 <i>Audit 03 Design Control Viamed 24 Aug 2016</i> Process: 7726 <i>Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016</i>

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	Revision Document ID25508 Date Revision 05 Mar 2018 Reviewed 05 Mar 2018	
7.3.10 The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes. Design and development files	Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 12 CE Files Revision Document ID58351 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016
7.4 Purchasing	DO NOT USE VM3COP04 Purchasing / suppliers Revision Document ID15473 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015 VM3COP20.29 Checking the Purchase Order Log Revision Document ID20588 Date Revision 13 Jun 2017 Reviewed 13 Jun 2017 VM3COP27.34 Sending Purchase Orders to Suppliers Revision Document ID17070 Date Revision 22 Jun 2016 Reviewed 22 Jun 2016 VM3COP04.01 QC06 Supplier Questionnaire ISO Questionnaire Viamed Blank	Process: 5850 Purchase Order Log 17 Feb 2016 Process: 7707 Send Purchase Orders To Suppliers 13 Jun 2016

	Revision Document ID21304 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017	
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 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	Top Level Document: VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns Revision Document ID31084 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection Revision Document ID31044 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 05 Purchasing suppliers Revision Document ID33536 Date Revision 15 Mar 2020 Reviewed 15 Mar 2020 Audit 09 Goods Inward and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021 Reviewed 12 Mar 2021	Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016

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; 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	Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection Revision Document ID31044 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns Revision Document ID31084 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 05 Purchasing suppliers Revision Document ID33536 Date Revision 15 Mar 2020 Reviewed 15 Mar 2020 Audit 09 Goods Inward and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021 Reviewed 12 Mar 2021 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
7.4.3 The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any	Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Revision Document ID31076 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 06 Measurement Control Viamed VST, Calibration, QA Stock Revision Document ID53615 Date Revision 11 Feb 2021	Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016

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	Reviewed 11 Feb 2021 Audit 09 Goods Inward and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021 Reviewed 12 Mar 2021	
7.5 Production and service provision		
7.5.1 Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of	Top Level Document: VOP 22 Picking and Packing Dispatch and Goods Out Revision Document ID31048 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Revision Document ID31076 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 06 Measurement Control Viamed VST, Calibration, QA Stock Revision Document ID53615 Date Revision 11 Feb 2021 Reviewed 11 Feb 2021 Top Level Document: VOP 08 Production, Reworks, New Production Revision Document ID31072 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 VM3COP20.37 Generating a New Service Visit Revision Document	Process: 7714 Audit 01 Picking Packing Viamed 24 Aug 2016 Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016 Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016 Process: 7727 Audit 15 Production Viamed 24 Aug 2016

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	ID17116 Date Revision 28 Jun 2016 Reviewed 28 Jun 2016 Audit 06 Calibration Revision Document ID43594 Date Revision 15 Sep 2020 Reviewed 15 Sep 2020 Audit 01 Picking packing Revision Document ID51629 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 15 Production Revision Document ID59614 Date Revision 11 May 2021 Reviewed 11 May 2021 Audit 24 Service Logs Revision Document ID41450 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Audit 09 Goods Inward and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021 Reviewed 12 Mar 2021	
7.5.2 The organization shall document requirements for cleanliness of product or contamination control of product if: a) product is cleaned by the organization prior to sterilization or its use; b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use; c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use;	Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO Revision Document ID41667 Date Revision 11 Aug 2020 Reviewed 11 Aug 2020 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016

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		
7.5.3 The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5). Installation activities	Resuscitation Unit and TC400 Maintenance TC400 Installation Instructions Revision Document ID8155 Date Revision 24 Mar 2011 Reviewed 24 Mar 2011 Resuscitation Unit Instructions for Use / Installation Ceratherm v3.01 Resuscitation Unit and TC400 Maintenance Revision Document ID8178 Date Revision 24 Mar 2011 Reviewed 24 Mar 2011 Resuscitation Unit Instructions for Use / User Manual Nufer Wall Mount Installation Revision Document ID1312 Date Revision 19 Mar 2007 Reviewed 19 Mar 2007 VM3COP51.20 Resuscitation Cabinet Installation Instructions Revision Document ID18221 Date Revision 12 Dec 2016 Reviewed 12 Dec 2016 Audit 24 Service Logs Revision Document ID41450 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
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.	Top Level Document: VM3COP50.13 Quality Control Tom Thumb Revision Document ID31154 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 09 Repairs and Servicing Revision Document ID31020 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019	Process: 5857 Customer Service Logs 17 Feb 2016 Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016

The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5). Servicing activities	VM3COP20.27 Annual Services for Resuscitation Cabinets Revision Document ID24509 Date Revision 06 Dec 2017 Reviewed 06 Dec 2017 VM3COP20.37 Generating a New Service Visit Revision Document ID17116 Date Revision 28 Jun 2016 Reviewed 28 Jun 2016 VM3COP50.12 Quality Control / Service Checks Tom Thumb Revision Document ID15367 Date Revision 05 Aug 2015 Reviewed 05 Aug 2015 Audit 24 Service Logs Revision Document ID41450 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Audit 11 Repairs, Servicing and Returns Revision Document ID41150 Date Revision 02 Aug 2020 Reviewed 02 Aug 2020 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Audit 14 Complaints and Corrective Actions Revision Document ID41228 Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	
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 ID41667 Date Revision 11 Aug 2020 Reviewed 11 Aug 2020	Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
7.5.6 The organization shall validate any processes for	Top Level Document: VOP 27 Software Validation Revision Document	Process: 7849 Review Product Failures New Codes 28 Sep 2017

production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently.

The organization shall document procedures for validation of processes including:

- a) defined criteria for review and approval of the processes;
- b) equipment qualification and qualification of personnel;
- c) use of specific methods, procedures and acceptance criteria;
- d) as appropriate, statistical techniques with rationale for sample sizes
- e) requirements for records (see 4.2.5);
- f) revalidation, including criteria for revalidation;
- g) approval of changes to the processes.

The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications.

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Top Level Document: VOP 15 Data and Information Analysis

Analysis

Revision Document

ID31056

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VM3COP18 Post Market Surveillance

Revision Document ID8106

Date Revision 21 Mar 2011

Reviewed 21 Mar 2011

Audit 03 Design Control

Revision Document

ID51631

Date Revision 13 Jan 2021

Reviewed 13 Jan 2021

Audit 24 Service Logs

Revision Document

ID41450

Date Revision 07 Aug 2020

Reviewed 07 Aug 2020

Audit 11 Repairs, Servicing and Returns

Revision Document

ID41150

Date Revision 02 Aug 2020

Reviewed 02 Aug 2020

Audit 10 Documentation Control

Revision Document

ID42704

Date Revision 01 Sep 2020

Reviewed 01 Sep 2020

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Software Validation Non Conformance

Product Risk Feedback Loop 15 Oct 2017

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 ID41667 Date Revision 11 Aug 2020 Reviewed 11 Aug 2020	
7.5.8 The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. 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.	Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Revision Document ID31076 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection Revision Document ID31044 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 09 Goods Inward	

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	and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021 Reviewed 12 Mar 2021 Audit 11 Repairs, Servicing and Returns Revision Document ID41150 Date Revision 02 Aug 2020 Reviewed 02 Aug 2020	
7.5.9 Traceability	VM3COP14.01 Disposition of Documents / Records. Revision Document ID15464 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015	
7.5.9.1 The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5). General	VM3COP14.01 Disposition of Documents / Records. Revision Document ID15464 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015 VM3COP23.00 EAN13 Barcodes to Stock and the Online Databases Revision Document ID8596 Date Revision 25 Aug 2011 Reviewed 25 Aug 2011 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 10 Documentation Control Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020	
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	Top Level Document: VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO Revision Document ID41667 Date Revision 11 Aug 2020 Reviewed 11 Aug 2020	

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		
7.5.10 The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5). Customer property	Top Level Document: VOP 09 Repairs and Servicing Revision Document ID31020 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 DO NOT USE VM3COP09 Repairs Revision Document ID8712 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 VM3COP20.03 Repair Procedures Goods in Revision Document ID13703 Date Revision 13 May 2014 Reviewed 13 May 2014 VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork Revision Document ID24753 Date Revision 21 Dec 2017 Reviewed 21 Dec 2017 VM3COP20.47 Collecting Repair Paperwork Revision Document ID17485 Date Revision 15 Sep 2016 Reviewed 15 Sep 2016 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 09 Goods Inward and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021	Process: 7684 Repairs Ready For Quote 18 Apr 2016 Process: 7685 Repairs Ready For Invoice 18 Apr 2016 Process: 5891 Processing Of Repair Quotes And Orders 25 Feb 2016 Process: 7693 Collect Repair Filing From Warehouse 22 Apr 2016

	Reviewed 12 Mar 2021 Audit 11 Repairs, Servicing and Returns Revision Document ID41150 Date Revision 02 Aug 2020 Reviewed 02 Aug 2020	
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	Top Level Document: VOP 09 Repairs and Servicing Revision Document ID31020 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Revision Document ID31076 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 VM3COP20.03 Repair Procedures Goods in Revision Document ID13703 Date Revision 13 May 2014 Reviewed 13 May 2014 VM3COP20.031 Viamed Repair Procedures Invoicing / customer paperwork Revision Document ID24753 Date Revision 21 Dec 2017 Reviewed 21 Dec 2017 Audit 01 Picking packing Revision Document ID51629 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	Process: 7684 Repairs Ready For Quote 18 Apr 2016 Process: 7685 Repairs Ready For Invoice 18 Apr 2016 Process: 5891 Processing Of Repair Quotes And Orders 25 Feb 2016
7.6 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.	Top Level Document: VOP 06 Measurement Control Viamed VST, Calibration, QA Stock Revision Document ID53615 Date Revision 11 Feb 2021 Reviewed 11 Feb 2021 DO NOT USE VM3COP11 Calibration	

The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

As necessary to ensure valid results, measuring equipment shall:

- a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5);
- b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5);
- c) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

The organization shall perform calibration or verification in accordance with documented procedures.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected.

Revision Document ID8713

[Date Revision 12 Oct 2011](#)

[Reviewed 12 Oct 2011](#)

Explanation Control of documents

Revision Document ID21322

[Date Revision 06 Aug 2017](#)

[Reviewed 06 Aug 2017](#)

Audit 06 Calibration

Revision Document ID43594

[Date Revision 15 Sep 2020](#)

[Reviewed 15 Sep 2020](#)

Audit 23 Analysis of Data

Revision Document ID41446

[Date Revision 07 Aug 2020](#)

[Reviewed 07 Aug 2020](#)

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

Top Level Document: VM3COP27.11 Performing a Technical File PMS and risk assessment
 Revision Document ID17824
 Date Revision 03 Nov 2016
 Reviewed 25 Jan 2021
Top Level Document: VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data
 Revision Document

Process: 7714
 Audit 01 Picking Packing Viamed 24 Aug 2016
Process: 7715
 Audit 02 Contract Review Viamed 24 Aug 2016
Process: 7716
 Audit 03 Design Control Viamed 24 Aug 2016
Process: 7717
 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
Process: 7718
 Audit 06 Calibration Viamed 24 Aug 2016
Process: 7720

determination of appropriate methods, including statistical techniques, and the extent of their use. General	ID53797 Date Revision 16 Feb 2021 Reviewed 16 Feb 2021 Top Level Document: VOP 15 Data and Information Analysis Revision Document ID31056 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 Audit 22 Post Market Surveillance Revision Document ID41428 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 DO NOT USE VM3COP13 Audits Revision Document ID8715 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011	Audit 08 Training Viamed 24 Aug 2016 Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016 Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7724 Audit 11 Repairs And Service Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016 Process: 7726 Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 Process: 7727 Audit 15 Production Viamed 24 Aug 2016 Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016 Process: 7729 Audit 19 Health And Safety Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Management Viamed 24 Aug 2016 Process: 7731 Audit 21 Audit Of Audit Viamed 24 Aug 2016 Process: 7732 Audit 22 Post Market Surveillance Viamed 24 Aug 2016 Process: 7733 Audit 23 Analysis Of Data Viamed 24 Aug 2016 Process: 7834 Financial Review 20 Sep 2017 Process: 7862 Review The Audit Calendar Screen 04 Oct 2017 Process: 27 Management Reviews And Quality Audits 16 Feb 2016 Process: 5877 Review Company Data 17 Feb 2016 Process: 7070 Management Review 09 Mar 2016 Process: 7830 Review Q.A. Failures Report 18 Sep 2017 Process: 7837 Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 Process: 7838 Review VIAMED Feedback - Customer
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Feedback Negative 23 Sep 2017
Process: 7839
 Review VIAMED Feedback - Customer Complaints 23 Sep 2017
Process: 7840
 Review VST Feedback - Customer Feedback Negative 23 Sep 2017
Process: 7841
 Review VST Feedback - Customer Complaints 23 Sep 2017
Process: 7842
 Review VIAMED Product Feedback Negative 23 Sep 2017
Process: 7843
 Review VST Product Feedback Negative 23 Sep 2017
Process: 7848
 Review ISO Scopes 27 Sep 2017
Process: 7849
 Review Product Failures New Codes 28 Sep 2017
Process: 7871
 Review Exclusion From Viamed 13485:2016 And VST 9001:2015 15 Oct 2017
Process: 7874
 Review For Latest Version Med Dev 2.12. 18 Oct 2017
Process: 7876
 Maintain Update Of ISO Route Maps 21 Oct 2017
Process: 7878
 Review Possible Upcoming Regulation Changes 22 Oct 2017

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 as post-production activities. The information gathered in

Top Level Document:
VM3COP27.11 Performing a Technical File PMS and risk assessment
 Revision Document
 ID17824
 Date Revision 03 Nov 2016
 Reviewed 25 Jan 2021
Top Level Document: VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data
 Revision Document
 ID53797
 Date Revision 16 Feb 2021
 Reviewed 16 Feb 2021
Management Review
 Revision Document
 ID30851
 Date Revision 18 Sep 2019

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	Reviewed 18 Sep 2019 Management reviews Revision Document ID19801 Date Revision 05 May 2017 Reviewed 05 May 2017 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Audit 22 Post Market Surveillance Revision Document ID41428 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 14 Complaints and Corrective Actions Revision Document ID41228 Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	
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: - receiving and recording information; - evaluating information to determine if the feedback constitutes a complaint; - investigating complaints; - determining the need to report the information to the appropriate regulatory authorities; - handling of complaint-related product; - determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation	Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd Revision Document ID31040 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd Revision Document ID31052 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 14 Complaints and Corrective Actions Revision Document ID41228 Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7743 Customer Complaints Paper File 26 Sep 2016

determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Complaint handling records shall be maintained (see 4.2.5). Complaint handling		
8.2.3 If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.5). Reporting to regulatory authorities	Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd Revision Document ID31040 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 14 Complaints and Corrective Actions Revision Document ID41228 Date Revision 03 Aug 2020 Reviewed 03 Aug 2020 MHRA Correspondence / RG2 Devices list Revision Document ID14763 Date Revision 12 Feb 2015 Reviewed 12 Feb 2015 MHRA Appendix A / Appendix B Class 1 Device Codes Revision Document ID4798 Date Revision 24 Oct 2008 Reviewed 24 Oct 2008 CE Guidance 19 Own Brand MHRA position obl Revision Document ID3656 Date Revision 29 Apr 2008 Reviewed 29 Apr 2008	Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7743 Customer Complaints Paper File 26 Sep 2016
8.2.4 The organization shall conduct internal audits at planned intervals to determine whether the quality 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;	Top Level Document: VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data Revision Document ID53797 Date Revision 16 Feb 2021 Reviewed 16 Feb 2021 Audit 01 Picking packing Revision Document ID51629 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 02 Contract Review and Sales Order	Process: 7714 Audit 01 Picking Packing Viamed 24 Aug 2016 Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016 Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 Process: 7718 Audit 06 Calibration Viamed 24 Aug 2016 Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016

b) is effectively implemented and maintained.

The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.

Internal audit

Processing

Revision Document

ID33205

Date Revision 08 Mar 2020

Reviewed 08 Mar 2020

Audit 06 Calibration

Revision Document

ID43594

Date Revision 15 Sep 2020

Reviewed 15 Sep 2020

Audit 08 Training, Competence and Human Resources

Revision Document

ID40199

Date Revision 13 Jul 2020

Reviewed 13 Jul 2020

Audit 09 Goods Inward and Product Identity

Revision Document

ID55437

Date Revision 12 Mar 2021

Reviewed 12 Mar 2021

Audit 10 Documentation Control

Revision Document

ID42704

Date Revision 01 Sep 2020

Reviewed 01 Sep 2020

Audit 20 Process verification to Management

Revision Document

ID41418

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Audit 11 Repairs, Servicing and Returns

Revision Document

ID41150

Date Revision 02 Aug 2020

Reviewed 02 Aug 2020

Audit 15 Production

Revision Document

ID59614

Date Revision 11 May 2021

Reviewed 11 May 2021

Audit 17 Internal Audits

Revision Document

ID41240

Date Revision 03 Aug 2020

Reviewed 03 Aug 2020

Audit 18 Management Review

Revision Document

ID41388

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Audit 19 Health and

Process: 7720

Audit 08 Training Viamed 24 Aug 2016

Process: 7721

Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016

Process: 7722

Audit 10 Documentation Control Viamed 24 Aug 2016

Process: 7723

Audit 10b Process Verification Viamed 24 Aug 2016

Process: 7725

Audit 12 CE Files Viamed 24 Aug 2016

Process: 7724

Audit 11 Repairs And Service Viamed 24 Aug 2016

Process: 7726

Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016

Process: 7727

Audit 15 Production Viamed 24 Aug 2016

Process: 7728

Audit 17 Internal Audits Viamed 24 Aug 2016

Process: 7729

Audit 19 Health And Safety Viamed 24 Aug 2016

Process: 7730

Audit 20 Process Verification To Management Viamed 24 Aug 2016

Process: 7731

Audit 21 Audit Of Audit Viamed 24 Aug 2016

Process: 7732

Audit 22 Post Market Surveillance Viamed 24 Aug 2016

Process: 7733

Audit 23 Analysis Of Data Viamed 24 Aug 2016

	Safety, Working Conditions and Building Fabric Issues Revision Document ID41398 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 21 Audit of Audit Revision Document ID41422 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 22 Post Market Surveillance Revision Document ID41428 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Audit 24 Service Logs Revision Document ID41450 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020 Explanation Employee Roles and Titles Revision Document ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017 DO NOT USE VM3COP13 Audits Revision Document ID8715 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 Audit Schedule Revision Document ID23221 Date Revision 24 Oct 2017 Reviewed 24 Oct 2017	
8.2.5 The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and	Top Level Document: VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data Revision Document ID53797 Date Revision 16 Feb 2021 Reviewed 16 Feb 2021 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020	Process: 27 Management Reviews And Quality Audits 16 Feb 2016

corrective action shall be taken, as appropriate. Monitoring and measurement of processes	Reviewed 07 Aug 2020 Audit 10 Documentation Control Revision Document ID42704 Date Revision 01 Sep 2020 Reviewed 01 Sep 2020	
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 personnel performing any inspection or testing. Monitoring and measurement of product	DO NOT USE VM3COP11 Calibration Revision Document ID8713 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 OLD DO NOT USE VM3COP29 Production Revision Document ID8727 Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 15 Production Revision Document ID59614 Date Revision 11 May 2021 Reviewed 11 May 2021	
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	Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd Revision Document ID31040 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP	Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7743 Customer Complaints Paper File 26 Sep 2016

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	19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd Revision Document ID31052 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 VM3COP10.02 Product Recall locate products out in the Field Revision Document ID23643 Date Revision 28 Oct 2017 Reviewed 28 Oct 2017 Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021 Audit 09 Goods Inward and Product Identity Revision Document ID55437 Date Revision 12 Mar 2021 Reviewed 12 Mar 2021 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	
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	Audit 07 Handling and Storage Revision Document ID58347 Date Revision 23 Apr 2021 Reviewed 23 Apr 2021	

be maintained (see 4.2.5). Actions in response to nonconforming product detected before delivery		
8.3.3 When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5). The organization shall document procedures for issuing advisory notices in 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	Top Level Document: VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd Revision Document ID31040 <i>Date Revision 30 Sep 2019</i> <i>Reviewed 30 Sep 2019</i> Audit 14 Complaints and Corrective Actions Revision Document ID41228 <i>Date Revision 03 Aug 2020</i> <i>Reviewed 03 Aug 2020</i>	
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 08 Production, Reworks, New Production Revision Document ID31072 <i>Date Revision 30 Sep 2019</i> <i>Reviewed 30 Sep 2019</i> Top Level Document: VOP 09 Repairs and Servicing Revision Document ID31020 <i>Date Revision 30 Sep 2019</i> <i>Reviewed 30 Sep 2019</i> Audit 20 Process verification to Managment Revision Document ID41418 <i>Date Revision 06 Aug 2020</i> <i>Reviewed 06 Aug 2020</i> Audit 11 Repairs, Servicing and Returns Revision Document ID41150 <i>Date Revision 02 Aug 2020</i> <i>Reviewed 02 Aug 2020</i>	
8.4 The organization shall	Top Level Document: VOP 13 Process Monitoring	

document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5). Analysis of data	System Reviews Audits Management Review Analysis Data Revision Document ID53797 Date Revision 16 Feb 2021 Reviewed 16 Feb 2021 Top Level Document: VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns Revision Document ID31084 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Top Level Document: VOP 15 Data and Information Analysis Revision Document ID31056 Date Revision 30 Sep 2019 Reviewed 30 Sep 2019 Audit 22 Post Market Surveillance Revision Document ID41428 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 23 Analysis of Data Revision Document ID41446 Date Revision 07 Aug 2020 Reviewed 07 Aug 2020	
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,	Top Level Document: VOP 10 Non Conformance, Corrective and Preventive Actions Revision Document ID46915 Date Revision 02 Nov 2020 Reviewed 02 Nov 2020 Audit 06 Calibration Revision Document ID43594 Date Revision 15 Sep 2020 Reviewed 15 Sep 2020 Audit 18 Management	

analysis of data, corrective actions, preventive actions and management review.

General

Review

Revision Document

ID41388

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Audit 22 Post Market

Surveillance

Revision Document

ID41428

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Audit 23 Analysis of Data

Revision Document

ID41446

Date Revision 07 Aug 2020

Reviewed 07 Aug 2020

Audit 21 Audit of Audit

Revision Document

ID41422

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

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:

- reviewing nonconformities (including complaints);
- determining the causes of nonconformities;
- evaluating the need for action to ensure that nonconformities do not recur;
- planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or

Top Level Document: VOP 10 Non Conformance, Corrective and Preventive Actions

Revision Document

ID46915

Date Revision 02 Nov 2020

Reviewed 02 Nov 2020

Audit 20 Process verification to Managment

Revision Document

ID41418

Date Revision 06 Aug 2020

Reviewed 06 Aug 2020

Audit 10 Documentation Control

Revision Document

ID42704

Date Revision 01 Sep 2020

Reviewed 01 Sep 2020

Audit 14 Complaints and Corrective Actions

Revision Document

ID41228

Date Revision 03 Aug 2020

Reviewed 03 Aug 2020

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: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; e) reviewing the effectiveness of the preventive action taken, as appropriate. Records of the results of any investigations and of action taken shall be maintained (see 4.2.5). Preventive action	Top Level Document: VOP 10 Non Conformance, Corrective and Preventive Actions Revision Document ID46915 Date Revision 02 Nov 2020 Reviewed 02 Nov 2020 Audit 20 Process verification to Managment Revision Document ID41418 Date Revision 06 Aug 2020 Reviewed 06 Aug 2020 Audit 14 Complaints and Corrective Actions Revision Document ID41228 Date Revision 03 Aug 2020 Reviewed 03 Aug 2020	Process: 7839 Review VIAMED Feedback - Customer Complaints 23 Sep 2017

Document ID	Sub Processes
ID31634	Viamed ISO 13485:2016 Scope

	Process: 7848 Review ISO Scopes 27 Sep 2017
ID41667	VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO Process: 7871 Review Exclusion From Viamed 13485:2016 And VST 9001:2015 15 Oct 2017
ID42704	Audit 10 Documentation Control Process: 10 Distribution Of Emails 16 Feb 2016 Process: 5939 Responsibility Allocation : Email ISP Routing 05 Mar 2016 Process: 5940 Thumb Nail Processor 07 Mar 2016 Process: 11 Distribution Of Mail 16 Feb 2016 Process: 6 Responsibility Allocation : Updating Contact Management System 16 Feb 2016 Process: 52 Software Verification Clear Down Backup Emails 16 Feb 2016 Process: 53 Emails 16 Feb 2016 Process: 7672 Off Site Backup 09 Mar 2016 Process: 7700 Domain Name Management 19 May 2016 Process: 9 Distribution Of Faxes 16 Feb 2016 Process: 15 Filing and Archiving 16 Feb 2016 Process: 7711 Import Bank CSV 01 Jul 2016 Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7693 Collect Repair Filing From Warehouse 22 Apr 2016 Process: 12 Responsibility Allocation : Sales And Technical Information Processing 16 Feb 2016 Process: 16 Responsibility Allocation : Photocopying 16 Feb 2016 Process: 5901 Link Call Log Contacts To The CRM 02 Mar 2016 Process: 7699 Shred Sensitive Paperwork In JL Office 19 May 2016 Process: 7705 Checking For Uploaded Files 08 Jun 2016 Process: 7754 Process: 7770 Audit 10 Documentation Control VST 08 Feb 2017 Process: 6938 Responsibility Allocation : Customer Database Updates 09 Mar 2016 Process: 6940 Responsibility Allocation : Customer Ongoing task List 09 Mar 2016 Process: 7090 Responsibility Allocation : Office Procedures 09 Mar 2016 Process: 7032 Responsibility Allocation : Document Requirements 09 Mar 2016 Process: 41 Responsibility Allocation : Documentation Control 16 Feb 2016 Process: 59 Out Of Date Documents 17 Feb 2016 Process: 5851 Duplicate Documents 17 Feb 2016 Process: 5852 Responsibility Allocation : Retention Of Records 17 Feb 2016 Process: 7124 Responsibility Allocation : Intrastats 09 Mar 2016 Process: 7125 Responsibility Allocation : Intrastats Urgent Problems 09 Mar 2016 Process: 7126 Intrastats Requested Page updates 09 Mar 2016 Process: 7127 Responsibility Allocation : Intrastats Unfinished in progress Processes 09 Mar 2016 Process: 7128 Responsibility Allocation : Intrastats Future Features needed 09 Mar 2016 Process: 7129 Intrastats Cross Reference Database Tables Updates 09 Mar 2016 Process: 7130 Intrastats Information for Intrastats and L Drive 09 Mar 2016 Process: 7131 Responsibility Allocation : Intrastats Opera 09 Mar 2016 Process: 7133 Responsibility Allocation : Intrastats Contact Manager 09 Mar 2016 Process: 7739 Intrastats Amendment Log 12 Sep 2016 Process: 5877 Review Company Data 17 Feb 2016 Process: 44 Secure Socket Level Certificate 16 Feb 2016 Process: 5890 Check Website ISO Documents 24 Feb 2016 Process: 7863 Maintain Repair Codes List 05 Oct 2017 Process: 7922 Back Up Emily's Accounts Docs 04 Jan 2019
ID30999	VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control Process: 5940 Thumb Nail Processor 07 Mar 2016 Process: 7827 Review The Quality Policy VST 16 Sep 2017 Process: 7828 Review The Quality Policy Viamed 16 Sep 2017 Process: 5934 Responsibility Allocation : Staff Training 05 Mar 2016 Process: 7032 Responsibility Allocation : Document Requirements 09 Mar 2016

	Process: 41 Responsibility Allocation : Documentation Control 16 Feb 2016 Process: 59 Out Of Date Documents 17 Feb 2016 Process: 5851 Duplicate Documents 17 Feb 2016 Process: 5852 Responsibility Allocation : Retention Of Records 17 Feb 2016 Process: 7130 Intrastats Information for Intrastats and L Drive 09 Mar 2016 Process: 5890 Check Website ISO Documents 24 Feb 2016 Process: 7200 Responsibility Allocation : ISO Issues 09 Mar 2016 Process: 7744 FDA Device Establishment Registration And Listing 28 Sep 2016
ID8700	Chart 27 Customer Complaints Chart 27 Process: 7743 Customer Complaints Paper File 26 Sep 2016
ID27474	VM3COP02.02 Viamed Company Responsibilitys organisation chart structure Process: 5877 Review Company Data 17 Feb 2016
ID41418	Audit 20 Process verification to Managment Process: 7701 AWS Amazon Web Services 23 May 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016 Process: 7827 Review The Quality Policy VST 16 Sep 2017 Process: 7828 Review The Quality Policy Viamed 16 Sep 2017 Process: 7771 Audit 10b Process Verification VST 08 Feb 2017 Process: 7778 Audit 20 Process Verification To Managment VST 08 Feb 2017 Process: 6866 Internal Process Verification Complete Systems Review 09 Mar 2016 Process: 7755 Fast Hosts Invoice 08 Dec 2016 Process: 7845 7.1.4 Environment Of Operations 25 Sep 2017 Process: 7846 ISO System Management Review 26 Sep 2017 Process: 7837 Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 Process: 7832 Cleardown Emailed Invoices 20 Sep 2017 Process: 7848 Review ISO Scopes 27 Sep 2017 Process: 7851 Software Validation Scan Un-QA Product To Order 01 Oct 2017 Process: 7852 Software Validation Expired Stock 01 Oct 2017 Process: 7853 Software Validation Non Sell Able Shelf 01 Oct 2017 Process: 7854 Software Validation In Production List 01 Oct 2017 Process: 7855 Software Validation - Production Lists 01 Oct 2017 Process: 7856 Software Validation Unchecked Orders 01 Oct 2017 Process: 7857 Software Validation Stock Tracking Check 01 Oct 2017 Process: 7858 Software Validation Attempt To QA Some Stock 01 Oct 2017 Process: 7861 Software Validation Of Training Documents Forced Reading 03 Oct 2017 Process: 7850 Software Validation Scan In Correct Product 01 Oct 2017 Process: 7871 Review Exclusion From Viamed 13485:2016 And VST 9001:2015 15 Oct 2017 Process: 7865 Software Validation Conflicting Audits 07 Oct 2017 Process: 7870 Software Validation Non Conformance Product Risk Feedback Loop 15 Oct 2017 Process: 7879 Software Validation Scheduled Tasks And Audits 22 Oct 2017 Process: 7875 Software Validation Document Control 20 Oct 2017 Process: 7880 Software Validation Out Of Date Documents 22 Oct 2017 Process: 7881 Software Validation - Live Orders 22 Oct 2017
ID16995	VM3COP27.17 Complete Auto_calender Issues Process: 27 Management Reviews And Quality Audits 16 Feb 2016
ID20131	VM3COP27.02 Collecting Emails and Distributing Process: 10 Distribution Of Emails 16 Feb 2016
ID53797	VOP 13 Process Monitoring System Reviews Audits Management Review Analysis Data Process: 55 Business Continuity Plan 17 Feb 2016 Process: 23 Company Objectives 16 Feb 2016 Process: 27 Management Reviews And Quality Audits 16 Feb 2016 Process: 7714 Audit 01 Picking Packing Viamed 24 Aug 2016 Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016 Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016

Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
Process: 7718 Audit 06 Calibration Viamed 24 Aug 2016
Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016
Process: 7720 Audit 08 Training Viamed 24 Aug 2016
Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016
Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016
Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016
Process: 7724 Audit 11 Repairs And Service Viamed 24 Aug 2016
Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016
Process: 7726 Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016
Process: 7727 Audit 15 Production Viamed 24 Aug 2016
Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016
Process: 7729 Audit 19 Health And Safety Viamed 24 Aug 2016
Process: 7730 Audit 20 Process Verification To Management Viamed 24 Aug 2016
Process: 7731 Audit 21 Audit Of Audit Viamed 24 Aug 2016
Process: 7732 Audit 22 Post Market Surveillance Viamed 24 Aug 2016
Process: 7733 Audit 23 Analysis Of Data Viamed 24 Aug 2016
Process: 6828
Process: 22 Company Policies 16 Feb 2016
Process: 7754
Process: 7762 Audit 01 Picking Packing VST 08 Feb 2017
Process: 7763 Audit 02 Contract Review VST 08 Feb 2017
Process: 7764 Audit 03 Design Control VST 08 Feb 2017
Process: 7765 Audit 05 Purchasing Suppliers VST 08 Feb 2017
Process: 7766 Audit 06 Calibration VST 08 Feb 2017
Process: 7767 Audit 07 Handling And Storage VST 08 Feb 2017
Process: 7768 Audit 08 Training VST 08 Feb 2017
Process: 7769 Audit 09 Goods Inward And Product Identity VST 08 Feb 2017
Process: 7770 Audit 10 Documentation Control VST 08 Feb 2017
Process: 7771 Audit 10b Process Verification VST 08 Feb 2017
Process: 7772 Audit 11 Repairs And Service VST 08 Feb 2017
Process: 7773 Audit 12 CE Files VST 08 Feb 2017
Process: 7774 Audit 14 Complaints And Corrective Actions VST 08 Feb 2017
Process: 7775 Audit 15 Production VST 08 Feb 2017
Process: 7776 Audit 17 Internal Audits VST 08 Feb 2017
Process: 7777 Audit 19 Health And Safety VST 08 Feb 2017
Process: 7778 Audit 20 Process Verification To Management VST 08 Feb 2017
Process: 7779 Audit 21 Audit Of Audit VST 08 Feb 2017
Process: 7780 Audit 22 Post Market Surveillance VST 08 Feb 2017
Process: 7781 Audit 23 Analysis Of Data VST 08 Feb 2017
Process: 7808 Ensure All Invoice Correctly Tagged 02 Jun 2017
Process: 6886 Responsibility Allocation : VIAMED Sales And Marketing Sales Viamed Medical Export 09 Mar 2016
Process: 6887 Responsibility Allocation : VIAMED Sales And Marketing Sales Viamed Automotive Export 09 Mar 2016
Process: 7204 Responsibility Allocation : VIAMED Board Directors Meeting Distributor Issues 09 Mar 2016
Process: 24 Responsibility Allocation : Compliance ISO Standards 16 Feb 2016
Process: 28 Supplier Review 16 Feb 2016
Process: 6865 Responsibility Allocation : Non Conformance Effectiveness 09 Mar 2016
Process: 6866 Internal Process Verification Complete Systems Review 09 Mar 2016
Process: 7172 Responsibility Allocation : CE Technical Files 09 Mar 2016
Process: 7782 Remove Started But Not Used Order Numbers 08 Feb 2017
Process: 7090 Responsibility Allocation : Office Procedures 09 Mar 2016
Process: 7138 Non Conformance Issues Any New QC21 Forms 09 Mar 2016
Process: 57 Temporary Stock Notices 17 Feb 2016
Process: 5854 Stock FAQ Admin List 17 Feb 2016
Process: 7043 Responsibility Allocation : Planning of product realization 09 Mar 2016

Process: 38 Audits Up to Date and Confirm next years Audit schedule 16 Feb 2016
Process: 5877 Review Company Data 17 Feb 2016
Process: 6904 Responsibility Allocation : Sales And Marketing Internal sales 09 Mar 2016
Process: 6944 Responsibility Allocation : Stock Meeting 09 Mar 2016
Process: 7846 ISO System Management Review 26 Sep 2017
Process: 7834 Financial Review 20 Sep 2017
Process: 26 Company Resources 16 Feb 2016
Process: 7070 Management Review 09 Mar 2016
Process: 7837 Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017
Process: 5887 Review ISO/EN Documents 24 Feb 2016
Process: 5889 Responsibility Allocation : Audit And Task - Audit 24 Feb 2016
Process: 7071 Post Market Surveillance 09 Mar 2016
Process: 7093 BSI Audits Calander 09 Mar 2016
Process: 7829
Process: 7670 Humanmed general Issues 09 Mar 2016
Process: 6821 Responsibility Allocation : VIAMED Management Meeting Supplier Review 09 Mar 2016
Process: 6831 Responsibility Allocation : VIAMED Management Meeting Supplier Review - Min / Max - Re-Orders 09 Mar 2016
Process: 6833 Responsibility Allocation : VIAMED Management Meeting MDA Recalls 09 Mar 2016
Process: 6834 Responsibility Allocation : VIAMED Management Meeting Additional Purchase Orders 09 Mar 2016
Process: 6836 Responsibility Allocation : VIAMED Management Meeting Research and Development rnd 09 Mar 2016
Process: 6920 Responsibility Allocation : VIAMED Sales And Marketing Price Lists UK 09 Mar 2016
Process: 6924 Responsibility Allocation : VIAMED Sales And Marketing Price Lists Export 09 Mar 2016
Process: 6935 Responsibility Allocation : VIAMED Sales And Marketing Products to be Marketed 09 Mar 2016
Process: 6936 Responsibility Allocation : VIAMED Sales And Marketing NHS Supplies Future Technology 09 Mar 2016
Process: 6941 Responsibility Allocation : VIAMED Sales And Marketing New Potential Products 09 Mar 2016
Process: 7039 Responsibility Allocation : Provision of Resources 09 Mar 2016
Process: 7187 Responsibility Allocation : VIAMED Board Directors Meeting Profiability 09 Mar 2016
Process: 7196 Responsibility Allocation : VIAMED Board Directors Meeting Stock Levels 09 Mar 2016
Process: 6871 ISO14001 Environmental management systems 09 Mar 2016
Process: 7848 Review ISO Scopes 27 Sep 2017
Process: 7862 Review The Audit Calender Screen 04 Oct 2017
Process: 7879 Software Validation Scheduled Tasks And Audits 22 Oct 2017
Process: 7876 Maintain Update Of ISO Route Maps 21 Oct 2017
Process: 7878 Review Possible Upcoming Regulation Changes 22 Oct 2017
Process: 7885 Audit 04 Accounts and Finance 23 Oct 2017
Process: 7886 Audit 18 Management Review Viamed 24 Oct 2017
Process: 7887 Audit 18 Management Review VST 24 Oct 2017
Process: 7889 Audit 24 Servicing Viamed 24 Oct 2017
Process: 7888 Review Processes Linked To VOPs And Audits 24 Oct 2017
Process: 7965 VST Feedback 29 Oct 2020
Process: 7964 Check Roles And Tasks For Incomplete Data 29 Oct 2020

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Audit 18 Management Review**Process: 55 Business Continuity Plan 17 Feb 2016****Process: 23 Company Objectives 16 Feb 2016****Process: 6813 Management Meeting Turnover Report 09 Mar 2016**

	Process: 27 Management Reviews And Quality Audits 16 Feb 2016 Process: 22 Company Policys 16 Feb 2016 Process: 7750 Meeting With Management 14 Oct 2016 Process: 7793 Team Review Meeting 16 Mar 2017 Process: 7753 Management Meeting Warehouse 22 Nov 2016 Process: 6861 Management Meeting Review Weekly Meeting 09 Mar 2016 Process: 7833 Importance Of Effective Quality Management 20 Sep 2017 Process: 7834 Financial Review 20 Sep 2017 Process: 26 Company Resources 16 Feb 2016 Process: 30 Responsibility Allocation : MHRA Licences And Notifications 16 Feb 2016 Process: 31 Responsibility Allocation : Notified Body Notifications 16 Feb 2016 Process: 32 MDALL Listings 16 Feb 2016 Process: 7057 Responsibility Allocation : Complaints and Vigilance Notifications 09 Mar 2016 Process: 7070 Management Review 09 Mar 2016 Process: 29 Responsibility Allocation : CMDCAS Updates And Licences 16 Feb 2016 Process: 5889 Responsibility Allocation : Audit And Task - Audit 24 Feb 2016 Process: 7744 FDA Device Establishment Registration And Listing 28 Sep 2016 Process: 7829 Process: 6871 ISO14001 Environmental management systems 09 Mar 2016 Process: 7874 Review For Latest Version Med Dev 2.12. 18 Oct 2017 Process: 7877 Disaster Planning 21 Oct 2017 Process: 7876 Maintain Update Of ISO Route Maps 21 Oct 2017 Process: 7878 Review Possible Upcoming Regulation Changes 22 Oct 2017 Process: 7886 Audit 18 Management Review Viamed 24 Oct 2017 Process: 7887 Audit 18 Management Review VST 24 Oct 2017 Process: 7890 New UPS Rates Needs Checking 24 Oct 2017 Process: 7888 Review Processes Linked To VOPs And Audits 24 Oct 2017 Process: 7895 FDA Device Establishment Registration 29 Oct 2017 Process: 7912 Review The Personel Information We Collect Or Store 20 Sep 2018 Process: 7913 Review Personnel Files 20 Sep 2018 Process: 7918 Backup Jeans Local Folder 08 Nov 2018 Process: 7964 Check Roles And Tasks For Incomplete Data 29 Oct 2020
ID31084	VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns Process: 6972 UPS Shipping Fuel Surcharge 09 Mar 2016 Process: 28 Supplier Review 16 Feb 2016 Process: 6960 Process: 7784 Check Returns Supplier Envitec 15 Feb 2017 Process: 7785 Check Returns Supplier Teledyne 15 Feb 2017 Process: 7786 Check Returns Supplier Maxtec 15 Feb 2017 Process: 7787 Check Returns All Supplier 15 Feb 2017
ID33536	Audit 05 Purchasing suppliers Process: 7707 Send Purchase Orders To Suppliers 13 Jun 2016 Process: 6972 UPS Shipping Fuel Surcharge 09 Mar 2016 Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016 Process: 5850 Purchase Order Log 17 Feb 2016 Process: 7751 VST Purchase Order Log 02 Nov 2016 Process: 7765 Audit 05 Purchasing Suppliers VST 08 Feb 2017 Process: 7794 V1000 Commissions Review 30 Mar 2017 Process: 7745 UPS Invoices Viamed 06 Oct 2016 Process: 7746 UPS Invoices VST 06 Oct 2016 Process: 7747 UPS Invoices Vandagraph 06 Oct 2016 Process: 7790 Humanmed Invoice them For Previous Month 10 Mar 2017 Process: 28 Supplier Review 16 Feb 2016 Process: 6960 Process: 5855 Purchase Order Requirements Teledyne 17 Feb 2016 Process: 5866 UPS Shipping Fuel Surcharge 17 Feb 2016 Process: 5868 Return Goods To Suppliers 17 Feb 2016

	Process: 6829 Supplier Review - Outstanding orders 09 Mar 2016 Process: 6832 Supplier Review Future orders 09 Mar 2016 Process: 6848 Process: 6952 Responsibility Allocation : Lost in Shipping Claims 09 Mar 2016 Process: 6971 Responsibility Allocation : Freight Courier Cost Request 09 Mar 2016 Process: 7679 Check Stock Requirements Supplier Teledyne 18 Apr 2016 Process: 7680 Check Stock Requirements Supplier Envitec 18 Apr 2016 Process: 7681 Check Stock Requirements Supplier Posey 18 Apr 2016 Process: 7682 Check Stock Requirements Supplier Bluepoint 18 Apr 2016 Process: 7784 Check Returns Supplier Envitec 15 Feb 2017 Process: 7785 Check Returns Supplier Teledyne 15 Feb 2017 Process: 7786 Check Returns Supplier Maxtec 15 Feb 2017 Process: 7787 Check Returns All Supplier 15 Feb 2017 Process: 34 Responsibility Allocation : Insurance Is Upto Date 16 Feb 2016 Process: 7683 Check Stock For Proforma 18 Apr 2016 Process: 7882 Purchase Payments 23 Oct 2017 Process: 7956 Teledyne Stock For Vandagraph 27 May 2020
ID53611	Audit 27 Software Validation Process: 52 Software Verification Clear Down Backup Emails 16 Feb 2016 Process: 7668 Responsibility Allocation : Upgrading Intrastats ISO Quality system 09 Mar 2016 Process: 7132 Responsibility Allocation : Intrastats Goldmine 09 Mar 2016 Process: 7851 Software Validation Scan Un-QA Product To Order 01 Oct 2017 Process: 7852 Software Validation Expired Stock 01 Oct 2017 Process: 7853 Software Validation Non Sell Able Shelf 01 Oct 2017 Process: 7854 Software Validation In Production List 01 Oct 2017 Process: 7855 Software Validation - Production Lists 01 Oct 2017 Process: 7856 Software Validation Unchecked Orders 01 Oct 2017 Process: 7857 Software Validation Stock Tracking Check 01 Oct 2017 Process: 7858 Software Validation Attempt To QA Some Stock 01 Oct 2017 Process: 7861 Software Validation Of Training Documents Forced Reading 03 Oct 2017 Process: 7850 Software Validation Scan In Correct Product 01 Oct 2017 Process: 7865 Software Validation Conflicting Audits 07 Oct 2017 Process: 7870 Software Validation Non Conformance Product Risk Feedback Loop 15 Oct 2017 Process: 7879 Software Validation Scheduled Tasks And Audits 22 Oct 2017 Process: 7875 Software Validation Document Control 20 Oct 2017 Process: 7880 Software Validation Out Of Date Documents 22 Oct 2017 Process: 7881 Software Validation - Live Orders 22 Oct 2017 Process: 7892 Audit 27 Software Validation 26 Oct 2017 Process: 7951 Server Review 05 Mar 2020
ID31064	VOP 27 Software Validation Process: 52 Software Verification Clear Down Backup Emails 16 Feb 2016 Process: 7851 Software Validation Scan Un-QA Product To Order 01 Oct 2017 Process: 7852 Software Validation Expired Stock 01 Oct 2017 Process: 7853 Software Validation Non Sell Able Shelf 01 Oct 2017 Process: 7854 Software Validation In Production List 01 Oct 2017 Process: 7855 Software Validation - Production Lists 01 Oct 2017 Process: 7856 Software Validation Unchecked Orders 01 Oct 2017 Process: 7857 Software Validation Stock Tracking Check 01 Oct 2017 Process: 7858 Software Validation Attempt To QA Some Stock 01 Oct 2017 Process: 7861 Software Validation Of Training Documents Forced Reading 03 Oct 2017 Process: 7850 Software Validation Scan In Correct Product 01 Oct 2017 Process: 7865 Software Validation Conflicting Audits 07 Oct 2017 Process: 7870 Software Validation Non Conformance Product Risk Feedback Loop 15 Oct 2017 Process: 7879 Software Validation Scheduled Tasks And Audits 22 Oct 2017

	Process: 7875 Software Validation Document Control 20 Oct 2017 Process: 7880 Software Validation Out Of Date Documents 22 Oct 2017 Process: 7881 Software Validation - Live Orders 22 Oct 2017 Process: 7892 Audit 27 Software Validation 26 Oct 2017
ID22684	VM3COP00.00 Viamed Quality Statement policy and objectives Process: 23 Company Objectives 16 Feb 2016 Process: 22 Company Polycys 16 Feb 2016 Process: 7828 Review The Quality Policy Viamed 16 Sep 2017 Process: 7833 Importance Of Effective Quality Management 20 Sep 2017
ID22062	VM3COP00.00 VST Quality Statement policy and objectives Process: 23 Company Objectives 16 Feb 2016 Process: 7827 Review The Quality Policy VST 16 Sep 2017 Process: 7833 Importance Of Effective Quality Management 20 Sep 2017
ID25632	VOP 17 Design Research and Development Process: 42 Responsibility Allocation : Design Documentation 16 Feb 2016 Process: 43 Responsibility Allocation : Product Post Market Survelance 16 Feb 2016 Process: 6975 Responsibility Allocation : Projects 09 Mar 2016 Process: 7045 Responsibility Allocation : Design and Development 09 Mar 2016
ID51631	Audit 03 Design Control Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 42 Responsibility Allocation : Design Documentation 16 Feb 2016 Process: 7764 Audit 03 Design Control VST 08 Feb 2017 Process: 7043 Responsibility Allocation : Planning of product realization 09 Mar 2016 Process: 7045 Responsibility Allocation : Design and Development 09 Mar 2016 Process: 7047 Responsibility Allocation : Production and service provision 09 Mar 2016 Process: 6942 Responsibility Allocation : Co ordination of Implementation 09 Mar 2016 Process: 7173 Responsibility Allocation : Material Generation 09 Mar 2016 Process: 5887 Review ISO/EN Documents 24 Feb 2016 Process: 7919 Send Debtors Overview To Derek 06 Dec 2018
ID41446	Audit 23 Analysis of Data Process: 27 Management Reviews And Quality Audits 16 Feb 2016 Process: 7733 Audit 23 Analysis Of Data Viamed 24 Aug 2016 Process: 7781 Audit 23 Analysis Of Data VST 08 Feb 2017 Process: 5877 Review Company Data 17 Feb 2016 Process: 6931 Customer Complaints 09 Mar 2016 Process: 7839 Review VIAMED Feedback - Customer Complaints 23 Sep 2017 Process: 7838 Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 Process: 26 Company Resources 16 Feb 2016 Process: 7070 Management Review 09 Mar 2016 Process: 7713 Review Roles And Responsibilitys 17 Aug 2016 Process: 7837 Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 Process: 7840 Review VST Feedback - Customer Feedback Negative 23 Sep 2017 Process: 7841 Review VST Feedback - Customer Complaints 23 Sep 2017 Process: 7842 Review VIAMED Product Feedback Negative 23 Sep 2017 Process: 7843 Review VST Product Feedback Negative 23 Sep 2017 Process: 7071 Post Market Surveillance 09 Mar 2016 Process: 7830 Review Q.A. Failures Report 18 Sep 2017 Process: 7849 Review Product Failures New Codes 28 Sep 2017 Process: 7930 Review Flow Of Data 12 Mar 2019
ID31096	VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks Process: 39 Enviromental Policy Document Review 16 Feb 2016 Process: 7741 Review Ethical Policy 14 Sep 2016 Process: 6839 Responsibility Allocation : Personnel Holidays and Time Adjustments 09 Mar 2016 Process: 5881 Training Records Review 18 Feb 2016

	Process: 5904 Responsibility Allocation : Taking On New Staff 02 Mar 2016 Process: 6837 Personnel Requirements and Training 09 Mar 2016 Process: 6877 Responsibility Allocation : Alarm Key Holders 09 Mar 2016 Process: 6906 Responsibility Allocation : Time Working Away 09 Mar 2016 Process: 6928 Responsibility Allocation : Staff 09 Mar 2016 Process: 7074 Process: 7042 Responsibility Allocation : Work Environment 09 Mar 2016 Process: 5934 Responsibility Allocation : Staff Training 05 Mar 2016 Process: 5874 Childcare Vouchers Edenred 17 Feb 2016 Process: 7753 Management Meeting Warehouse 22 Nov 2016 Process: 34 Responsibility Allocation : Insurance Is Upto Date 16 Feb 2016 Process: 5869 Responsibility Allocation : Legal Company Car Registration 17 Feb 2016 Process: 6841 Responsibility Allocation : Grants 09 Mar 2016 Process: 6843 Process: 6861 Management Meeting Review Weekly Meeting 09 Mar 2016 Process: 30 Responsibility Allocation : MHRA Licences And Notifications 16 Feb 2016 Process: 31 Responsibility Allocation : Notified Body Notifications 16 Feb 2016 Process: 32 MDALL Listings 16 Feb 2016 Process: 7033 Responsibility Allocation : Management commitment to ISO 09 Mar 2016 Process: 7037 Responsibility Allocation : Responsibility, authority and communication 09 Mar 2016 Process: 7057 Responsibility Allocation : Complaints and Vigilance Notifications 09 Mar 2016 Process: 7713 Review Roles And Responsibility's 17 Aug 2016 Process: 7837 Review External Parties Influencing The QMS VST / Viamed 23 Sep 2017 Process: 29 Responsibility Allocation : CMDCAS Updates And Licences 16 Feb 2016 Process: 7848 Review ISO Scopes 27 Sep 2017 Process: 7891 Fire Alarm Evacuation Drill 25 Oct 2017 Process: 7908 Private Information Data 27 Jul 2018 Process: 7907 Annual Review Doc Management 27 Jul 2018 Process: 7937 Diversity Impact Assessment 27 Jun 2019 Process: 7961 R D Room - Tidy, Empty Bins, Remove Cups. Caution Around Oxygen Supply 05 Oct 2020
ID17423	VM3COP02 Organisation Responsibilities Viamed Process: 6967 Responsibility Allocation : VIAMED Stock Meeting Repairs Review - Pulse Oximetry Sensors 09 Mar 2016 Process: 7900 Royal Mail - Mail Retention Form 29 Mar 2018
ID31036	VOP 18 Maintenance Building, Fabric and Infrastructure Process: 5856 Cleaning The Kitchen 17 Feb 2016 Process: 5853 Vacuuming Of The Office, Hall And Meeting Room 17 Feb 2016 Process: 5900 Cleaning Of Office Windows 25 Feb 2016 Process: 5878 Empty Office Bins 18 Feb 2016 Process: 5912 Responsibility Allocation : Main Recycle Bins 03 Mar 2016 Process: 5906 Empty Paper Bins 03 Mar 2016 Process: 7805 Empty Kitchen Bins 22 May 2017 Process: 5909 Empty Warehouse Bins 03 Mar 2016 Process: 7706 Update Virus Software And Scan For Viruses 10 Jun 2016 Process: 7802 Clean Kitchen Sides 22 May 2017 Process: 7803 Dishwashing 22 May 2017 Process: 7804 Sweep Kitchen Floor 22 May 2017 Process: 7806 Watering Plants 22 May 2017 Process: 7807 Process: 54 Responsibility Allocation : Gents Toilets 17 Feb 2016 Process: 5907 Hoover Warehouse 03 Mar 2016 Process: 5908 Sweep Warehouse 03 Mar 2016 Process: 5910 Clean Duckets 03 Mar 2016 Process: 5911 Clear Cardboard 03 Mar 2016 Process: 7698 Clean Toilets 17 May 2016

	Process: 7131 Responsibility Allocation : Intrastats Opera 09 Mar 2016 Process: 7133 Responsibility Allocation : Intrastats Contact Manager 09 Mar 2016 Process: 7132 Responsibility Allocation : Intrastats Goldmine 09 Mar 2016 Process: 7896 Tree In Car Park 22 Dec 2017
ID21800	VM3COP19 Health and Safety Process: 6855 Risk Assessment HSE 09 Mar 2016
ID22429	Viamed Top Level Quality Objectives Process: 23 Company Objectives 16 Feb 2016
ID33748	VOP 03 Contract Review, Enquires, Office Processes Process: 5 Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016 Process: 10 Distribution Of Emails 16 Feb 2016 Process: 36 Emailing Of Invoices 16 Feb 2016 Process: 5892 Checking EBay And Amazon For Orders And Messages 25 Feb 2016 Process: 5894 Checking Of Active List 25 Feb 2016 Process: 7 Responsibility Allocation : Checking Of Sales Orders 16 Feb 2016 Process: 5943 Check Cardea And Multiquote 08 Mar 2016 Process: 5891 Processing Of Repair Quotes And Orders 25 Feb 2016 Process: 11 Distribution Of Mail 16 Feb 2016 Process: 2 Answering Telephones 16 Feb 2016 Process: 37 West Yorkshire Ambulance Stock 16 Feb 2016 Process: 5948 Adding New Accounts To Opera 08 Mar 2016 Process: 5949 Filling Credit Card Slips 08 Mar 2016 Process: 6 Responsibility Allocation : Updating Contact Management System 16 Feb 2016 Process: 5895 Responsibility Allocation : Completing Office Job List 25 Feb 2016 Process: 5875 Check Paypal For Orders 17 Feb 2016 Process: 5944 Responsibility Allocation : Chasing Lost Customers 08 Mar 2016 Process: 3 Responsibility Allocation : Meeting And Greeting Visitors To The Company 16 Feb 2016 Process: 4 Responsibility Allocation : Assisting With Refreshments For Visitors 16 Feb 2016 Process: 7676 PDFing Of Invoices Viamed 17 Mar 2016 Process: 9 Distribution Of Faxes 16 Feb 2016 Process: 7696 Send VIAMED Delivery Notifications 28 Apr 2016 Process: 5857 Customer Service Logs 17 Feb 2016 Process: 5893 Answering Website Questions 25 Feb 2016 Process: 7678 Check Catalog 360 Circle For Quotes And Orders 08 Apr 2016 Process: 15 Filing and Archiving 16 Feb 2016 Process: 5899 Proforma And Quote Chasing 25 Feb 2016 Process: 7710 Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016 Process: 7707 Send Purchase Orders To Suppliers 13 Jun 2016 Process: 14 Fax Paper 16 Feb 2016 Process: 5882 Responsibility Allocation : Send Post To Humanmed 24 Feb 2016 Process: 7734 Responsibility Allocation : Humanmed Order Processing 25 Aug 2016 Process: 5850 Purchase Order Log 17 Feb 2016 Process: 7693 Collect Repair Filing From Warehouse 22 Apr 2016 Process: 7677 Process: 5897 Responsibility Allocation : Franking Mail 25 Feb 2016 Process: 21 Office Sales Projects 16 Feb 2016 Process: 7709 Delivered not Invoiced 28 Jun 2016 Process: 8 Responsibility Allocation : Order And Status Liaison With Customers 16 Feb 2016 Process: 12 Responsibility Allocation : Sales And Technical Information Processing 16 Feb 2016 Process: 16 Responsibility Allocation : Photocopying 16 Feb 2016 Process: 17 Process: 20 Processing Of Mail Shots 16 Feb 2016 Process: 5896 Responsibility Allocation : Ensuring ORD's Are Taken To Goods Out And Invoices Are Retrieved 25 Feb 2016 Process: 5901 Link Call Log Contacts To The CRM 02 Mar 2016

Process: 5913 Check For Humanmed Orders In Logistics Mailbox 03 Mar 2016
Process: 5947 Responsibility Allocation : Search For Distributors 08 Mar 2016
Process: 6958 Responsibility Allocation : Shipped Order Queries 09 Mar 2016
Process: 7686 Thorough Checking Of Awaiting Action Tray 21 Apr 2016
Process: 7699 Shred Sensitive Paperwork In JL Office 19 May 2016
Process: 7705 Checking For Uploaded Files 08 Jun 2016
Process: 7712 Review Inward Payments 01 Jul 2016
Process: 7735 Ensure SOR's Are Followed Up 01 Sep 2016
Process: 7751 VST Purchase Order Log 02 Nov 2016
Process: 7758 Check For GHX Orders 17 Jan 2017
Process: 7760 Send Service Offers 31 Jan 2017
Process: 7761 Send VST Delivery Notifications 01 Feb 2017
Process: 7783 PDF VST Invoices And Purchase Orders 10 Feb 2017
Process: 7792 Shipped Order Success Report 13 Mar 2017
Process: 7795 Answering UK Web Questions 27 Apr 2017
Process: 7822 Review Oxylink Stock 26 Jul 2017
Process: 5876 E.Commerce Cardea And Multiquote 17 Feb 2016
Process: 5873 Distributor Contract Reviews 17 Feb 2016
Process: 5885 Responsibility Allocation : Monthly Reports 24 Feb 2016
Process: 6938 Responsibility Allocation : Customer Database Updates 09 Mar 2016
Process: 6940 Responsibility Allocation : Customer Ongoing task List 09 Mar 2016
Process: 6956 Responsibility Allocation : Sales Order Issues 09 Mar 2016
Process: 5866 UPS Shipping Fuel Surcharge 17 Feb 2016
Process: 6952 Responsibility Allocation : Lost in Shipping Claims 09 Mar 2016
Process: 6971 Responsibility Allocation : Freight Courier Cost Request 09 Mar 2016
Process: 7692 Responsibility Allocation : Take Complete Repair Paperwork To Office 22 Apr 2016
Process: 7796 Review Franking Label Errors 08 May 2017
Process: 6916 Responsibility Allocation : Service exisiting 09 Mar 2016
Process: 6917 Responsibility Allocation : Service extension 09 Mar 2016
Process: 7863 Maintain Repair Codes List 05 Oct 2017
Process: 7890 New UPS Rates Needs Checking 24 Oct 2017
Process: 7893 VST Price Lists 28 Oct 2017
Process: 7894 VST Customer Agreements 28 Oct 2017
Process: 7901 UPS Exceptions Checkup 20 Apr 2018
Process: 7959 Audit 16 Sales And Marketing Viamed 28 Sep 2020

ID33205

Audit 02 Contract Review and Sales Order Processing

Process: 5 Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016
Process: 36 Emailing Of Invoices 16 Feb 2016
Process: 5892 Checking EBay And Amazon For Orders And Messages 25 Feb 2016
Process: 5894 Checking Of Active List 25 Feb 2016
Process: 7 Responsibility Allocation : Checking Of Sales Orders 16 Feb 2016
Process: 5943 Check Cardea And Multiquote 08 Mar 2016
Process: 5891 Processing Of Repair Quotes And Orders 25 Feb 2016
Process: 2 Answering Telephones 16 Feb 2016
Process: 37 West Yorkshire Ambulance Stock 16 Feb 2016
Process: 5945 Responsibility Allocation : Sending Samples 08 Mar 2016
Process: 5946 Responsibility Allocation : Sending Sale Or Returns 08 Mar 2016
Process: 5948 Adding New Accounts To Opera 08 Mar 2016
Process: 5949 Filling Credit Card Slips 08 Mar 2016
Process: 5895 Responsibility Allocation : Completing Office Job List 25 Feb 2016
Process: 5875 Check Paypal For Orders 17 Feb 2016
Process: 7675 Responsibility Allocation : Ordering Demo Stock For Humanmed Reps 11 Mar 2016
Process: 5944 Responsibility Allocation : Chasing Lost Customers 08 Mar 2016
Process: 3 Responsibility Allocation : Meeting And Greeting Visitors To The Company 16 Feb 2016

Process: 4 Responsibility Allocation : Assisting With Refreshments For Visitors 16 Feb 2016
Process: 7676 PDFing Of Invoices Viamed 17 Mar 2016
Process: 7696 Send VIAMED Delivery Notifications 28 Apr 2016
Process: 5893 Answering Website Questions 25 Feb 2016
Process: 7678 Check Catalog 360 Circle For Quotes And Orders 08 Apr 2016
Process: 5899 Proforma And Quote Chasing 25 Feb 2016
Process: 7710 Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016
Process: 14 Fax Paper 16 Feb 2016
Process: 5882 Responsibility Allocation : Send Post To Humanmed 24 Feb 2016
Process: 7715 Audit 02 Contract Review Viamed 24 Aug 2016
Process: 7734 Responsibility Allocation : Humanmed Order Processing 25 Aug 2016
Process: 7677
Process: 5897 Responsibility Allocation : Franking Mail 25 Feb 2016
Process: 7709 Delivered not Invoiced 28 Jun 2016
Process: 6954 Back Orders Review - By Customer 09 Mar 2016
Process: 8 Responsibility Allocation : Order And Status Liaison With Customers 16 Feb 2016
Process: 5896 Responsibility Allocation : Ensuring ORD's Are Taken To Goods Out And Invoices Are Retrieved 25 Feb 2016
Process: 5913 Check For Humanmed Orders In Logistics Mailbox 03 Mar 2016
Process: 5947 Responsibility Allocation : Search For Distributors 08 Mar 2016
Process: 6958 Responsibility Allocation : Shipped Order Queries 09 Mar 2016
Process: 7686 Thorough Checking Of Awaiting Action Tray 21 Apr 2016
Process: 7712 Review Inward Payments 01 Jul 2016
Process: 7735 Ensure SOR's Are Followed Up 01 Sep 2016
Process: 7758 Check For GHX Orders 17 Jan 2017
Process: 7761 Send VST Delivery Notifications 01 Feb 2017
Process: 7783 PDF VST Invoices And Purchase Orders 10 Feb 2017
Process: 7795 Answering UK Web Questions 27 Apr 2017
Process: 7822 Review Oxylink Stock 26 Jul 2017
Process: 7791 Price List Check 10 Mar 2017
Process: 7763 Audit 02 Contract Review VST 08 Feb 2017
Process: 7808 Ensure All Invoice Correctly Tagged 02 Jun 2017
Process: 5872 Check Sale Or Returns Export 17 Feb 2016
Process: 5871 Check Sale Or Returns 17 Feb 2016
Process: 5876 E.Commerce Cardea And Multiquote 17 Feb 2016
Process: 7782 Remove Started But Not Used Order Numbers 08 Feb 2017
Process: 6956 Responsibility Allocation : Sales Order Issues 09 Mar 2016
Process: 6921 Responsibility Allocation : Customer pricing agreements 09 Mar 2016
Process: 6922
Process: 6959 Responsibility Allocation : Sales Forward Orders Review 09 Mar 2016
Process: 7801 VST Price Review 17 May 2017
Process: 5905 Responsibility Allocation : Price Checking 02 Mar 2016
Process: 6950
Process: 7697 Yearly Pricing Review 09 May 2016
Process: 7670 Humanmed general Issues 09 Mar 2016
Process: 7872 Embargo Countries NOT Allowed To Sell To 16 Oct 2017
Process: 7893 VST Price Lists 28 Oct 2017
Process: 7894 VST Customer Agreements 28 Oct 2017
Process: 7936 B2B Router / Peppol Responsibilitys 19 Jun 2019
Process: 7941 Check Leaflets, Letterhead And Other Paperwork To See If The Correct BSI Logo Is In Use. Remove All Old If Found. 23 Sep 2019
Process: 7953 Vandagraph Delivery Notifications 26 May 2020
Process: 7954 Vandagraph Email Of Invoices 26 May 2020
Process: 7955 Vandagraph Shipper SignOff Collection 26 May 2020

ID31040

VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd
Process: 7743 Customer Complaints Paper File 26 Sep 2016
Process: 7671 Humanmed Non Conformances 09 Mar 2016

	Process: 6931 Customer Complaints 09 Mar 2016 Process: 7839 Review VIAMED Feedback - Customer Complaints 23 Sep 2017 Process: 7838 Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 Process: 7070 Management Review 09 Mar 2016 Process: 7840 Review VST Feedback - Customer Feedback Negative 23 Sep 2017 Process: 7841 Review VST Feedback - Customer Complaints 23 Sep 2017 Process: 7842 Review VIAMED Product Feedback Negative 23 Sep 2017 Process: 7843 Review VST Product Feedback Negative 23 Sep 2017 Process: 7174 Process: 7175 Process: 7179 Process: 7874 Review For Latest Version Med Dev 2.12. 18 Oct 2017
ID41236	Audit 16 Sales and Marketing Process: 21 Office Sales Projects 16 Feb 2016 Process: 17 Process: 40 Responsibility Allocation : Calender 16 Feb 2016 Process: 5870 Book Arab Health 17 Feb 2016 Process: 19 Maintaining Leaflet Stocks 16 Feb 2016 Process: 20 Processing Of Mail Shots 16 Feb 2016 Process: 5873 Distributor Contract Reviews 17 Feb 2016 Process: 5885 Responsibility Allocation : Monthly Reports 24 Feb 2016 Process: 5883 Responsibility Allocation : Monthly Sales Report 24 Feb 2016 Process: 6888 Viamed Automotive UK 09 Mar 2016 Process: 6898 GHX Web Pricing 09 Mar 2016 Process: 5884 Responsibility Allocation : Monthly Report 24 Feb 2016 Process: 5886 Responsibility Allocation : Monthly Report 24 Feb 2016 Process: 6891 Responsibility Allocation : Exhibitions Co-ordinator 09 Mar 2016 Process: 7909 EAN GTIN Online Database 06 Aug 2018 Process: 7920 Sales Warnings 20 Dec 2018 Process: 7927 Contract Pricing Review 14 Feb 2019 Process: 7926 Sales Forecasts Export 22 Jan 2019 Process: 7921 VST Bags And Grey Sensor 03 Jan 2019 Process: 7925 Providing Ebay Feedback 16 Jan 2019 Process: 7916 Google Webmaster Tools 16 Oct 2018 Process: 7931 Competitor Pricing 14 Mar 2019 Process: 7949 Sales Projects Send To Sales Team 04 Mar 2020 Process: 7947 8010004 - JJ-CCR Oxygen Sensor Orders 04 Mar 2020 Process: 7948 8010006 - REVo Oxygen Sensor Orders 04 Mar 2020 Process: 7950 Envitec Oxygen Sensor Parts Stock Check 05 Mar 2020 Process: 7959 Audit 16 Sales And Marketing Viamed 28 Sep 2020 Process: 7960 Audit 16 Sales And Marketing VST 28 Sep 2020
ID31076	VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Process: 6973 Responsibility Allocation : Stock Transfers. (QC19) 09 Mar 2016 Process: 7675 Responsibility Allocation : Ordering Demo Stock For Humanmed Reps 11 Mar 2016 Process: 5872 Check Sale Or Returns Export 17 Feb 2016 Process: 5871 Check Sale Or Returns 17 Feb 2016 Process: 5855 Purchase Order Requirements Teledyne 17 Feb 2016 Process: 5858 Opera Stock Adjustments 17 Feb 2016 Process: 5868 Return Goods To Suppliers 17 Feb 2016 Process: 5935 Stock Allocations 05 Mar 2016 Process: 6829 Supplier Review - Outstanding orders 09 Mar 2016 Process: 6832 Supplier Review Future orders 09 Mar 2016 Process: 6840 Process: 6848 Process: 6850 Current Stock Levels 09 Mar 2016 Process: 6945 Missing Stock or Adjustments 09 Mar 2016

	Process: 6955 Production Requirements 09 Mar 2016 Process: 7046 Responsibility Allocation : Stock Purchasing 09 Mar 2016 Process: 7051 Responsibility Allocation : Control of nonconforming product 09 Mar 2016 Process: 7673 Check Expiry Dated Stock 09 Mar 2016 Process: 7679 Check Stock Requirements Supplier Teledyne 18 Apr 2016 Process: 7680 Check Stock Requirements Supplier Envitec 18 Apr 2016 Process: 7681 Check Stock Requirements Supplier Posey 18 Apr 2016 Process: 7682 Check Stock Requirements Supplier Bluepoint 18 Apr 2016 Process: 7687 Vandagraph Duckets 21 Apr 2016 Process: 7688 Process: 7689 Move Stock From QA Shelf To Stock Shelf Monday 21 Apr 2016 Process: 7694 Move Stock From QA Shelf To Stock Shelf Tuesday 28 Apr 2016 Process: 7695 Top Up Quick Shipping Shelves 28 Apr 2016 Process: 7708 Acorn 0014904 17 Jun 2016 Process: 7798 Orders And Items Shipped Per Month 10 May 2017 Process: 6961 Responsibility Allocation : VIAMED Stock Meeting Purchase Order Requirements 09 Mar 2016 Process: 7683 Check Stock For Proforma 18 Apr 2016 Process: 6968 Responsibility Allocation : VIAMED Stock Meeting Repairs Review - General 09 Mar 2016 Process: 6949 Responsibility Allocation : VIAMED Stock Meeting QA Processing 09 Mar 2016 Process: 6948 Responsibility Allocation : VIAMED Stock Meeting Stock Processing 09 Mar 2016 Process: 6947 Responsibility Allocation : VIAMED Stock Meeting Stock Queries 09 Mar 2016 Process: 7830 Review Q.A. Failures Report 18 Sep 2017 Process: 7864 ESD Work Stations 07 Oct 2017 Process: 7873 On Site Environment Review 18 Oct 2017 Process: 7866 Oxygen Cylinder Check 13 Oct 2017 Process: 7897 Daily O2 Sensors Returns 04 Jan 2018 Process: 7909 EAN GTIN Online Database 06 Aug 2018 Process: 7943 Review Stocks Of 8000004 01 Oct 2019 Process: 7944 Sealant, Glues, Greases, Sprays, Gases And Tapes You Use In Production, Service And Repairs For Viamed And VST 09 Oct 2019 Process: 7962 VST Supplier QA Results 28 Oct 2020
ID18641	VM3COP20.01 Post In Distributing the Post Process: 11 Distribution Of Mail 16 Feb 2016 Process: 5882 Responsibility Allocation : Send Post To Humanmed 24 Feb 2016
ID40199	Audit 08 Training, Competence and Human Resources Process: 7720 Audit 08 Training Viamed 24 Aug 2016 Process: 6839 Responsibility Allocation : Personnel Holidays and Time Adjustments 09 Mar 2016 Process: 5881 Training Records Review 18 Feb 2016 Process: 5904 Responsibility Allocation : Taking On New Staff 02 Mar 2016 Process: 5936 Wages Calculations 05 Mar 2016 Process: 6837 Personnel Requirements and Training 09 Mar 2016 Process: 6851 Review Accident Book 09 Mar 2016 Process: 6877 Responsibility Allocation : Alarm Key Holders 09 Mar 2016 Process: 6906 Responsibility Allocation : Time Working Away 09 Mar 2016 Process: 6928 Responsibility Allocation : Staff 09 Mar 2016 Process: 7074 Process: 7759 Health Declaration Sheet 23 Jan 2017 Process: 7768 Audit 08 Training VST 08 Feb 2017 Process: 5934 Responsibility Allocation : Staff Training 05 Mar 2016 Process: 6841 Responsibility Allocation : Grants 09 Mar 2016 Process: 7070 Management Review 09 Mar 2016 Process: 7713 Review Roles And Responsibilitys 17 Aug 2016

	Process: 7883 Appraisal 23 Oct 2017 Process: 7884 Pay Review 23 Oct 2017 Process: 7908 Private Information Data 27 Jul 2018 Process: 7907 Annual Review Doc Management 27 Jul 2018 Process: 7937 Diversity Impact Assessment 27 Jun 2019 Process: 7951 Server Review 05 Mar 2020
ID41398	Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Process: 5941 Responsibility Allocation : Replace Main Server 07 Mar 2016 Process: 45 Responsibility Allocation : Main Server Status 16 Feb 2016 Process: 46 Responsibility Allocation : Backup Server Status 16 Feb 2016 Process: 7704 Responsibility Allocation : Computer Failure Diagnostics 24 May 2016 Process: 5856 Cleaning The Kitchen 17 Feb 2016 Process: 7729 Audit 19 Health And Saftey Viamed 24 Aug 2016 Process: 5853 Vacuuming Of The Office, Hall And Meeting Room 17 Feb 2016 Process: 5900 Cleaning Of Office Windows 25 Feb 2016 Process: 39 Enviromental Policy Document Review 16 Feb 2016 Process: 7741 Review Ethical Policy 14 Sep 2016 Process: 5878 Empty Office Bins 18 Feb 2016 Process: 5912 Responsibility Allocation : Main Recycle Bins 03 Mar 2016 Process: 7821 Controlled Waste Description And Transfer 15 Jun 2017 Process: 7820 North Yorkshire Council Waste Tranfer 15 Jun 2017 Process: 5906 Empty Paper Bins 03 Mar 2016 Process: 7805 Empty Kitchen Bins 22 May 2017 Process: 5909 Empty Warehouse Bins 03 Mar 2016 Process: 7042 Responsibility Allocation : Work Environment 09 Mar 2016 Process: 7706 Update Virus Software And Scan For Viruses 10 Jun 2016 Process: 7802 Clean Kitchen Sides 22 May 2017 Process: 7803 Dishwashing 22 May 2017 Process: 7804 Sweep Kitchen Floor 22 May 2017 Process: 7806 Watering Plants 22 May 2017 Process: 7807 Process: 7777 Audit 19 Health And Saftey VST 08 Feb 2017 Process: 54 Responsibility Allocation : Gents Toilets 17 Feb 2016 Process: 5907 Hoover Warehouse 03 Mar 2016 Process: 5908 Sweep Warehouse 03 Mar 2016 Process: 5910 Clean Duckets 03 Mar 2016 Process: 5911 Clear Cardboard 03 Mar 2016 Process: 7687 Vandagraph Duckets 21 Apr 2016 Process: 7698 Clean Toilets 17 May 2016 Process: 6849 First Aid 09 Mar 2016 Process: 6855 Risk Assessment HSE 09 Mar 2016 Process: 6856 Fire Alarms 09 Mar 2016 Process: 7092 Process: 56 Warehouse Outside Heating Guard 17 Feb 2016 Process: 5919 Check Out Side Drain 05 Mar 2016 Process: 5921 Clearing Water Downstairs 05 Mar 2016 Process: 7120 General Maintenance Requirements 09 Mar 2016 Process: 7742 Boiler Check 26 Sep 2016 Process: 7756 Carbon Monoxide Alarm 05 Jan 2017 Process: 48 Responsibility Allocation : Internet 16 Feb 2016 Process: 49 Responsibility Allocation : Wifi 16 Feb 2016 Process: 50 Responsibility Allocation : Guest Access Wifi 16 Feb 2016 Process: 51 Responsibility Allocation : Printers 16 Feb 2016 Process: 5903 Responsibility Allocation : Weather Station 02 Mar 2016 Process: 7121 Responsibility Allocation : General Computer Maintenance 09 Mar 2016 Process: 7178 Responsibility Allocation : Systems Innovation 09 Mar 2016 Process: 6843

	Process: 7835 Electrics Need Checking 20 Sep 2017 Process: 7836 Central Heating For Winter 20 Sep 2017 Process: 7847 Health And Safety Review 26 Sep 2017 Process: 7864 ESD Work Stations 07 Oct 2017 Process: 7867 Bandsaw Checklist 13 Oct 2017 Process: 7868 Pillar Drill Checklist 13 Oct 2017 Process: 7869 Hand Drill Checklist 13 Oct 2017 Process: 7891 Fire Alarm Evacuation Drill 25 Oct 2017 Process: 7896 Tree In Car Park 22 Dec 2017 Process: 7910 Review CCTV Warning Signs 20 Sep 2018 Process: 7928 Fire Test Points Checking 21 Feb 2019 Process: 7929 Emergency Lighting And Fire Extinguishers 21 Feb 2019 Process: 7911 Review Security Of The Special Category Personal Data 20 Sep 2018 Process: 7961 R D Room - Tidy, Empty Bins, Remove Cups. Caution Around Oxygen Supply 05 Oct 2020
ID29373	VM3COP02.02 VST Company Responsibility organisation chart structure Process: 5877 Review Company Data 17 Feb 2016
ID31052	VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 6931 Customer Complaints 09 Mar 2016 Process: 7070 Management Review 09 Mar 2016 Process: 7965 VST Feedback 29 Oct 2020
ID41422	Audit 21 Audit of Audit Process: 7731 Audit 21 Audit Of Audit Viamed 24 Aug 2016 Process: 7779 Audit 21 Audit Of Audit VST 08 Feb 2017 Process: 38 Audits Up to Date and Confirm next years Audit schedule 16 Feb 2016 Process: 7093 BSI Audits Calander 09 Mar 2016 Process: 7670 Humanmed general Issues 09 Mar 2016 Process: 7862 Review The Audit Calender Screen 04 Oct 2017
ID41428	Audit 22 Post Market Surveillance Process: 7732 Audit 22 Post Market Surveillance Viamed 24 Aug 2016 Process: 43 Responsibility Allocation : Product Post Market Survelance 16 Feb 2016 Process: 7780 Audit 22 Post Market Surveillance VST 08 Feb 2017 Process: 6889 Responsibility Allocation : Post Market Surveillance 09 Mar 2016 Process: 7809 Pro-Active Marketing 06 Jun 2017 Process: 7810 Research Activities 06 Jun 2017 Process: 5863 Responsibility Allocation : Sales Meetings UK 17 Feb 2016 Process: 5864 Responsibility Allocation : Sales Meeting EX 17 Feb 2016
ID45125	Management Review Blank Minutes 20xx Process: 7846 ISO System Management Review 26 Sep 2017
ID31024	VOP 12 Training Process: 7750 Meeting With Management 14 Oct 2016 Process: 7793 Team Review Meeting 16 Mar 2017 Process: 5934 Responsibility Allocation : Staff Training 05 Mar 2016 Process: 7833 Importance Of Effective Quality Management 20 Sep 2017 Process: 7845 7.1.4 Environment Of Operations 25 Sep 2017 Process: 7883 Appraisal 23 Oct 2017
ID14696	Process: 6972 UPS Shipping Fuel Surcharge 09 Mar 2016
ID17155	VM3COP03.05 Procedures for customer returning goods on our UPS account number Process: 5879 Responsibility Allocation : Customer Returning Goods On Our UPS Account 18 Feb 2016
ID31032	VOP 16 Health and Safety, Company Personnel Manual Process: 7821 Controlled Waste Description And Transfer 15 Jun 2017 Process: 7820 North Yorkshire Council Waste Tranfer 15 Jun 2017

	Process: 6851 Review Accident Book 09 Mar 2016 Process: 7759 Health Declaration Sheet 23 Jan 2017 Process: 6849 First Aid 09 Mar 2016 Process: 6855 Risk Assessment HSE 09 Mar 2016 Process: 6856 Fire Alarms 09 Mar 2016 Process: 7092 Process: 56 Warehouse Outside Heating Guard 17 Feb 2016 Process: 5919 Check Out Side Drain 05 Mar 2016 Process: 5921 Clearing Water Downstairs 05 Mar 2016 Process: 7120 General Maintenance Requirements 09 Mar 2016 Process: 7742 Boiler Check 26 Sep 2016 Process: 7756 Carbon Monoxide Alarm 05 Jan 2017 Process: 7835 Electrics Need Checking 20 Sep 2017 Process: 7836 Central Heating For Winter 20 Sep 2017 Process: 7847 Health And Safety Review 26 Sep 2017 Process: 7867 Bandsaw Checklist 13 Oct 2017 Process: 7868 Pillar Drill Checklist 13 Oct 2017 Process: 7869 Hand Drill Checklist 13 Oct 2017
ID58347	Audit 07 Handling and Storage Process: 6973 Responsibility Allocation : Stock Transfers. (QC19) 09 Mar 2016 Process: 7719 Audit 07 Handling And Storage Viamed 24 Aug 2016 Process: 7767 Audit 07 Handling And Storage VST 08 Feb 2017 Process: 5858 Opera Stock Adjustments 17 Feb 2016 Process: 5935 Stock Allocations 05 Mar 2016 Process: 6840 Process: 6850 Current Stock Levels 09 Mar 2016 Process: 6945 Missing Stock or Adjustments 09 Mar 2016 Process: 7046 Responsibility Allocation : Stock Purchasing 09 Mar 2016 Process: 7051 Responsibility Allocation : Control of nonconforming product 09 Mar 2016 Process: 7673 Check Expiry Dated Stock 09 Mar 2016 Process: 7688 Process: 7689 Move Stock From QA Shelf To Stock Shelf Monday 21 Apr 2016 Process: 7694 Move Stock From QA Shelf To Stock Shelf Tuesday 28 Apr 2016 Process: 7695 Top Up Quick Shipping Shelves 28 Apr 2016 Process: 7873 On Site Environment Review 18 Oct 2017 Process: 7866 Oxygen Cylinder Check 13 Oct 2017 Process: 7903 Empty Warehouse Depleted Sensor Bin 17 Jul 2018 Process: 7904 Check Weeee Waste Pallet And Sensor Bin 17 Jul 2018 Process: 7902 Empty Depleted Sensor Bin From The Offic 17 Jul 2018 Process: 7942 Do We Have Service Manual / QA For All Our Stock Coming In. 23 Sep 2019 Process: 7940 Review The Tom Thumb Grease Date 18 Sep 2019 Process: 7944 Sealant, Glues, Greases, Sprays, Gases And Tapes You Use In Production, Service And Repairs For Viamed And VST 09 Oct 2019
ID53615	VOP 06 Measurement Control Viamed VST, Calibration, QA Stock Process: 7718 Audit 06 Calibration Viamed 24 Aug 2016 Process: 7091 Calibration Index 09 Mar 2016
ID59614	Audit 15 Production Process: 7727 Audit 15 Production Viamed 24 Aug 2016 Process: 7736 Production Start Job List 03 Sep 2016 Process: 7737 Production In Production List 03 Sep 2016 Process: 7738 Production Statistics 03 Sep 2016 Process: 7775 Audit 15 Production VST 08 Feb 2017 Process: 6845 Responsibility Allocation : Quarantine Production 09 Mar 2016 Process: 6955 Production Requirements 09 Mar 2016 Process: 7169 Responsibility Allocation : Production 09 Mar 2016 Process: 7170 Responsibility Allocation : Production Production Schedule 09 Mar 2016

	Process: 7171 Responsibility Allocation : Production Production Problems 09 Mar 2016 Process: 7072 Responsibility Allocation : Manufacturing Processes 09 Mar 2016
ID31008	VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment Process: 5939 Responsibility Allocation : Email ISP Routing 05 Mar 2016 Process: 5941 Responsibility Allocation : Replace Main Server 07 Mar 2016 Process: 45 Responsibility Allocation : Main Server Status 16 Feb 2016 Process: 46 Responsibility Allocation : Backup Server Status 16 Feb 2016 Process: 52 Software Verification Clear Down Backup Emails 16 Feb 2016 Process: 53 Emails 16 Feb 2016 Process: 7672 Off Site Backup 09 Mar 2016 Process: 6813 Management Meeting Turnover Report 09 Mar 2016 Process: 7700 Domain Name Management 19 May 2016 Process: 7701 AWS Amazon Web Services 23 May 2016 Process: 7704 Responsibility Allocation : Computer Failure Diagnostics 24 May 2016 Process: 48 Responsibility Allocation : Internet 16 Feb 2016 Process: 49 Responsibility Allocation : Wifi 16 Feb 2016 Process: 50 Responsibility Allocation : Guest Access Wifi 16 Feb 2016 Process: 51 Responsibility Allocation : Printers 16 Feb 2016 Process: 5903 Responsibility Allocation : Weather Station 02 Mar 2016 Process: 6838 Opera Negative Stock 09 Mar 2016 Process: 7121 Responsibility Allocation : General Computer Maintenance 09 Mar 2016 Process: 7124 Responsibility Allocation : Intrastats 09 Mar 2016 Process: 7125 Responsibility Allocation : Intrastats Urgent Problems 09 Mar 2016 Process: 7126 Intrastats Requested Page updates 09 Mar 2016 Process: 7127 Responsibility Allocation : Intrastats Unfinished in progress Processes 09 Mar 2016 Process: 7128 Responsibility Allocation : Intrastats Future Features needed 09 Mar 2016 Process: 7129 Intrastats Cross Reference Database Tables Updates 09 Mar 2016 Process: 7178 Responsibility Allocation : Systems Innovation 09 Mar 2016 Process: 7739 Intrastats Amendment Log 12 Sep 2016 Process: 7755 Fast Hosts Invoice 08 Dec 2016 Process: 44 Secure Socket Level Certificate 16 Feb 2016 Process: 7668 Responsibility Allocation : Upgrading Intrastats ISO Quality system 09 Mar 2016 Process: 7832 Cleardown Emailed Invoices 20 Sep 2017 Process: 7823 Saftey Tester Data 02 Aug 2017
ID31044	VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection Process: 5938 Responsibility Allocation : Receive Goods 05 Mar 2016 Process: 5898 Processing Depleted Sensors 25 Feb 2016 Process: 5879 Responsibility Allocation : Customer Returning Goods On Our UPS Account 18 Feb 2016 Process: 7826 Goods In Processes 06 Sep 2017 Process: 7859 Check POR Files For Items Delivered But Not Removed From File 02 Oct 2017
ID31020	VOP 09 Repairs and Servicing Process: 7684 Repairs Ready For Quote 18 Apr 2016 Process: 7685 Repairs Ready For Invoice 18 Apr 2016 Process: 7690 Ship Repairs 21 Apr 2016 Process: 7752 SRS Folder 22 Nov 2016 Process: 6847 Responsibility Allocation : Quarantine Repairs 09 Mar 2016 Process: 6862 Current Repairs 09 Mar 2016 Process: 7048 Control of monitoring and measuring devices 09 Mar 2016 Process: 7674 Check Repairs Ready For Invoice List 10 Mar 2016 Process: 7814 Responsibility Allocation : Viamed Repairs 06 Jun 2017 Process: 7811 Responsibility Allocation : General Area 06 Jun 2017 Process: 7812 Responsibility Allocation : Vandagraph Repairs 06 Jun 2017 Process: 7813 Responsibility Allocation : VST Repairs 06 Jun 2017 Process: 7815 Responsibility Allocation : Product Types To Relevant Person 06 Jun 2017

	Process: 7942 Do We Have Service Manual / QA For All Our Stock Coming In. 23 Sep 2019 Process: 7940 Review The Tom Thumb Grease Date 18 Sep 2019
ID31072	VOP 08 Production, Reworks, New Production Process: 7736 Production Start Job List 03 Sep 2016 Process: 7737 Production In Production List 03 Sep 2016 Process: 7738 Production Statistics 03 Sep 2016 Process: 6845 Responsibility Allocation : Quarantine Production 09 Mar 2016 Process: 7169 Responsibility Allocation : Production 09 Mar 2016 Process: 7170 Responsibility Allocation : Production Production Schedule 09 Mar 2016 Process: 7171 Responsibility Allocation : Production Production Problems 09 Mar 2016 Process: 7072 Responsibility Allocation : Manufacturing Processes 09 Mar 2016 Process: 6962 Responsibility Allocation : VIAMED Stock Meeting Returns Overview 09 Mar 2016
ID55437	Audit 09 Goods Inward and Product Identity Process: 5938 Responsibility Allocation : Receive Goods 05 Mar 2016 Process: 7721 Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016 Process: 7826 Goods In Processes 06 Sep 2017 Process: 7792 Shipped Order Success Report 13 Mar 2017 Process: 7769 Audit 09 Goods Inward And Product Identity VST 08 Feb 2017 Process: 6969 Responsibility Allocation : VIAMED Stock Meeting 'Goods In' Review 09 Mar 2016 Process: 57 Temporary Stock Notices 17 Feb 2016 Process: 5854 Stock FAQ Admin List 17 Feb 2016 Process: 7181 Responsibility Allocation : Product Catagories 09 Mar 2016 Process: 6894 Product Cross References 09 Mar 2016 Process: 6838 Opera Negative Stock 09 Mar 2016 Process: 7830 Review Q.A. Failures Report 18 Sep 2017 Process: 7859 Check POR Files For Items Delivered But Not Removed From File 02 Oct 2017 Process: 7897 Daily O2 Sensors Returns 04 Jan 2018 Process: 7898 Stamp Deliveries 30 Jan 2018 Process: 7903 Empty Warehouse Depleted Sensor Bin 17 Jul 2018 Process: 7914 Proofs of Delivery 02 Oct 2018 Process: 7915 Reserve Stock Review 02 Oct 2018 Process: 7917 Human Med Purchase Order 18 Oct 2018 Process: 7923 Review Of Credits Received From Suppliers 08 Jan 2019 Process: 7943 Review Stocks Of 8000004 01 Oct 2019 Process: 7957 Warehouse Requests 29 May 2020 Process: 7962 VST Supplier QA Results 28 Oct 2020
ID22016	VM3COP20.31 Export Order Processing Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017
ID20049	VM3COP03.01 Order Processing Priorities Process: 5 Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017
ID47862	VM3COP20.30 UK Order Processing Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017
ID22266	VM3COP03.07 Humanmed Order Checking Process: 7 Responsibility Allocation : Checking Of Sales Orders 16 Feb 2016 Process: 7734 Responsibility Allocation : Humanmed Order Processing 25 Aug 2016 Process: 7709 Delivered not Invoiced 28 Jun 2016
ID24775	VM3COP03.08 Humanmed Order Processing Process: 5 Responsibility Allocation : Processing Of Sales Orders 16 Feb 2016 Process: 7734 Responsibility Allocation : Humanmed Order Processing 25 Aug 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017
ID34889	VM3COP20.32 Order Checking Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017

ID51629	Audit 01 Picking packing Process: 7714 Audit 01 Picking Packing Viamed 24 Aug 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017 Process: 5859 Review Un-shipped Parcels 17 Feb 2016 Process: 6970 Process: 7691 Ship Sale Or Returns 21 Apr 2016 Process: 7762 Audit 01 Picking Packing VST 08 Feb 2017 Process: 7796 Review Franking Label Errors 08 May 2017 Process: 7797 Check Order Are Being Picked In Priority Order 10 May 2017 Process: 7798 Orders And Items Shipped Per Month 10 May 2017 Process: 7860 Goods Out Picking 03 Oct 2017
ID41150	Audit 11 Repairs, Servicing and Returns Process: 5898 Processing Depleted Sensors 25 Feb 2016 Process: 5879 Responsibility Allocation : Customer Returning Goods On Our UPS Account 18 Feb 2016 Process: 5857 Customer Service Logs 17 Feb 2016 Process: 7724 Audit 11 Repairs And Service Viamed 24 Aug 2016 Process: 7684 Repairs Ready For Quote 18 Apr 2016 Process: 7685 Repairs Ready For Invoice 18 Apr 2016 Process: 7690 Ship Repairs 21 Apr 2016 Process: 7748 Check Repair Orders 10 Oct 2016 Process: 7749 Check Repair Quotes 10 Oct 2016 Process: 7752 SRS Folder 22 Nov 2016 Process: 7760 Send Service Offers 31 Jan 2017 Process: 7772 Audit 11 Repairs And Service VST 08 Feb 2017 Process: 6847 Responsibility Allocation : Quarantine Repairs 09 Mar 2016 Process: 6862 Current Repairs 09 Mar 2016 Process: 7138 Non Conformance Issues Any New QC21 Forms 09 Mar 2016 Process: 7674 Check Repairs Ready For Invoice List 10 Mar 2016 Process: 7692 Responsibility Allocation : Take Complete Repair Paperwork To Office 22 Apr 2016 Process: 6916 Responsibility Allocation : Service exisiting 09 Mar 2016 Process: 6917 Responsibility Allocation : Service extension 09 Mar 2016 Process: 7823 Saftey Tester Data 02 Aug 2017 Process: 7905 Generate RMA Box, Link Items And Add Faults 17 Jul 2018 Process: 7906 Request RMA Based On The RMA Boxes 17 Jul 2018
ID26885	VM3COP27.31 Processing Proforma Invoices and Quotations Process: 7710 Responsibility Allocation : Proforma And Quote Processing 29 Jun 2016
ID13695	VM3COP20.05 New Orders - How to enter into Opera Viamed Process: 7936 B2B Router / Peppol Responsibilitys 19 Jun 2019
ID21314	Process: 6828
ID41228	Audit 14 Complaints and Corrective Actions Process: 7726 Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 Process: 6828 Process: 7743 Customer Complaints Paper File 26 Sep 2016 Process: 7774 Audit 14 Complaints And Corrective Actions VST 08 Feb 2017 Process: 6865 Responsibility Allocation : Non Conformance Effectiveness 09 Mar 2016 Process: 7199 Non Conformities Review 09 Mar 2016 Process: 7671 Humanmed Non Conformances 09 Mar 2016 Process: 6931 Customer Complaints 09 Mar 2016 Process: 7839 Review VIAMED Feedback - Customer Complaints 23 Sep 2017 Process: 7838 Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017 Process: 7840 Review VST Feedback - Customer Feedback Negative 23 Sep 2017 Process: 7841 Review VST Feedback - Customer Complaints 23 Sep 2017 Process: 7842 Review VIAMED Product Feedback Negative 23 Sep 2017

	Process: 7843 Review VST Product Feedback Negative 23 Sep 2017 Process: 7849 Review Product Failures New Codes 28 Sep 2017 Process: 7934 Test Website Questions 02 May 2019 Process: 7965 VST Feedback 29 Oct 2020
ID61390	Audit 04 Accounts and Finance Process: 7702 Responsibility Allocation : Vandagraph Pay Pay Issue Refund 23 May 2016 Process: 7703 Vandagraph Pay Pal Retrieve Funds 23 May 2016 Process: 5915 Opera Sales Ledger Close 05 Mar 2016 Process: 7740 Weights Per Region Needed To Submit EC Sales List 13 Sep 2016 Process: 5929 HMRC Intrastats Sales Data 05 Mar 2016 Process: 7799 Opera Purchase Ledger Close 11 May 2017 Process: 7800 Opera Nominal Ledger Close 11 May 2017 Process: 5937 Review the Delivered Not Invoiced Reports 05 Mar 2016 Process: 5865 Vandagraph Loan 17 Feb 2016 Process: 5867 Accounts On Stop 17 Feb 2016 Process: 5874 Childcare Vouchers Edenred 17 Feb 2016 Process: 5914 End Of Year Reports For Accountants 04 Mar 2016 Process: 5916 Bank Details Opera reports entered Intrastats 05 Mar 2016 Process: 5917 Fill in Cashbook / Bank Rec for previous Month 05 Mar 2016 Process: 5918 Journals for the End of Month accounts 05 Mar 2016 Process: 5920 Responsibility Allocation : Cheques To Bank - Fill in Paying in Book 05 Mar 2016 Process: 5922 Credit Cards Expenses Calculations 05 Mar 2016 Process: 5923 Credits Note Processing 05 Mar 2016 Process: 5924 Export Cheques sent by Currency Lodgement 05 Mar 2016 Process: 5925 Customs Clearance 05 Mar 2016 Process: 5926 Responsibility Allocation : Petty Cash Expenses receipts and cash 05 Mar 2016 Process: 5927 Responsibility Allocation : Accounts Filing 05 Mar 2016 Process: 5928 Responsibility Allocation : Filing Cabinets 05 Mar 2016 Process: 5930 VAT Return Viamed 05 Mar 2016 Process: 5931 Purchase Invoices in to Opera 05 Mar 2016 Process: 5932 Remit Processing and entry into Opera 05 Mar 2016 Process: 5933 Responsibility Allocation : Sales Accounts Reminders 05 Mar 2016 Process: 5942 Chase the Debtors viamed 08 Mar 2016 Process: 6819 Supplier Payments and Invoice processing 09 Mar 2016 Process: 6822 Process: 6876 Issues for Accountants - P11D Form re Benefits to Revenue and Customs 09 Mar 2016 Process: 6946 Accounts Debtors Review - Export 09 Mar 2016 Process: 6951 Accounts Debtors Review - UK 09 Mar 2016 Process: 7192 Process: 7084 Responsibility Allocation : Accounts Issues 09 Mar 2016 Process: 7195 Responsibility Allocation : Loans between companies 09 Mar 2016 Process: 7788 Petty Cash Reconciliation 02 Mar 2017 Process: 7789 Withdraw Funds From Paypal 02 Mar 2017 Process: 7817 Issues For Accountants - Check suggested invoice report in operas 13 Jun 2017 Process: 7818 Issues For Accountants - Check Purchasing Journals to see if VAT handled correctly Previous Month 13 Jun 2017 Process: 7819 Issues For Accountant - Check Contra account 8000 and clear it 13 Jun 2017 Process: 7824 Chase The Debtors VST 27 Aug 2017 Process: 7708 Acorn 0014904 17 Jun 2016 Process: 5869 Responsibility Allocation : Legal Company Car Registration 17 Feb 2016 Process: 7831 Intrastats Debtors And Creditor Figures 18 Sep 2017 Process: 7885 Audit 04 Accounts and Finance 23 Oct 2017 Process: 7899 Region Checker 06 Feb 2018 Process: 7900 Royal Mail - Mail Retention Form 29 Mar 2018 Process: 7901 UPS Exceptions Checkup 20 Apr 2018

	Process: 7920 Sales Warnings 20 Dec 2018 Process: 7927 Contract Pricing Review 14 Feb 2019 Process: 7919 Send Debtors Overview To Derek 06 Dec 2018 Process: 7924 PDFing Of Invoices Vandagraph 11 Jan 2019 Process: 7932 Check Debtors Report 15 Mar 2019 Process: 7933 Purchasing Invoice Processing 22 Mar 2019 Process: 7935 PCI DSS Compliance 03 Jun 2019 Process: 7938 VAT Return Vandagraph 22 Jul 2019 Process: 7939 VAT Return VST 22 Jul 2019 Process: 7945 Xero Review Sales Contacts 05 Feb 2020 Process: 7946 Xero Merge Customers That Are Duplicates 05 Feb 2020 Process: 7952 Check Xero To Barclays Bank Statements End On Month GBP, USD And Euro Viamed 06 Mar 2020 Process: 7958 Exchange Rate In To Intrastats 03 Sep 2020 Process: 7966 Xero Sync 10 Mar 2021
ID58351	Audit 12 CE Files Process: 7725 Audit 12 CE Files Viamed 24 Aug 2016 Process: 7773 Audit 12 CE Files VST 08 Feb 2017 Process: 24 Responsibility Allocation : Compliance ISO Standards 16 Feb 2016 Process: 7172 Responsibility Allocation : CE Technical Files 09 Mar 2016 Process: 7071 Post Market Surveillance 09 Mar 2016
ID20588	VM3COP20.29 Checking the Purchase Order Log Process: 5850 Purchase Order Log 17 Feb 2016
ID17070	VM3COP27.34 Sending Purchase Orders to Suppliers Process: 7707 Send Purchase Orders To Suppliers 13 Jun 2016
ID43594	Audit 06 Calibration Process: 7718 Audit 06 Calibration Viamed 24 Aug 2016 Process: 7766 Audit 06 Calibration VST 08 Feb 2017 Process: 7048 Control of monitoring and measuring devices 09 Mar 2016 Process: 7091 Calibration Index 09 Mar 2016
ID41450	Audit 24 Service Logs Process: 5857 Customer Service Logs 17 Feb 2016 Process: 7760 Send Service Offers 31 Jan 2017 Process: 7889 Audit 24 Servicing Viamed 24 Oct 2017
ID31048	VOP 22 Picking and Packing Dispatch and Goods Out Process: 5945 Responsibility Allocation : Sending Samples 08 Mar 2016 Process: 5946 Responsibility Allocation : Sending Sale Or Returns 08 Mar 2016 Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017 Process: 5859 Review Un-shipped Parcels 17 Feb 2016 Process: 6954 Back Orders Review - By Customer 09 Mar 2016 Process: 6970 Process: 7691 Ship Sale Or Returns 21 Apr 2016 Process: 7748 Check Repair Orders 10 Oct 2016 Process: 7749 Check Repair Quotes 10 Oct 2016 Process: 7797 Check Order Are Being Picked In Priority Order 10 May 2017 Process: 6969 Responsibility Allocation : VIAMED Stock Meeting 'Goods In' Review 09 Mar 2016 Process: 7860 Goods Out Picking 03 Oct 2017
ID24509	VM3COP20.27 Annual Services for Resuscitation Cabinets Process: 5857 Customer Service Logs 17 Feb 2016
ID8596	VM3COP23.00 EAN13 Barcodes to Stock and the Online Databases Process: 7909 EAN GTIN Online Database 06 Aug 2018
ID8712	DO NOT USE VM3COP09 Repairs Process: 7684 Repairs Ready For Quote 18 Apr 2016

	Process: 7685 Repairs Ready For Invoice 18 Apr 2016 Process: 7814 Responsibility Allocation : Viamed Repairs 06 Jun 2017
ID13703	VM3COP20.03 Repair Procedures Goods in Process: 5891 Processing Of Repair Quotes And Orders 25 Feb 2016
ID17485	VM3COP20.47 Collecting Repair Paperwork Process: 7693 Collect Repair Filing From Warehouse 22 Apr 2016
ID41240	Audit 17 Internal Audits Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016 Process: 7776 Audit 17 Internal Audits VST 08 Feb 2017
ID46915	VOP 10 Non Conformance, Corrective and Preventive Actions Process: 7199 Non Conformities Review 09 Mar 2016 Process: 7069 Responsibility Allocation : Corrective Actions 09 Mar 2016 Process: 7849 Review Product Failures New Codes 28 Sep 2017 Process: 7874 Review For Latest Version Med Dev 2.12. 18 Oct 2017