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

Version Date: 10 Nov 2025

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4.1	Top Level Document:	Process: 8057
Quality management	QMS Route Map	Emergency Services Show 29 Dec 2023
system	Viamed Ltd	
	ISO13485_2016	
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	**Date Revision 27 Oct	
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	Revision Document	
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Revision Document

ID164833

Date Revision 14 Oct

2024 Reviewed 04 Nov

2024

Top Level Document:

VM3COP02.02 Viamed

Company

Responsibilitys

organisation chart

structure

Revision Document

ID167103

Date Revision 06 Nov

2024 Reviewed 06 Nov

2024

Top Level Document:

Viamed Top Level

Quality Objectives

Viamed Objectives

Revision Document

ID185333

Date Revision 14 May

2025 Reviewed 14 May

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BS EN ISO 13485-2016

Revision Document

ID19400

Date Revision 27 Mar

2017 Reviewed 27 Mar

2017

BS5750 Viamed

Revision Document

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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

VM3COP00.01 Company objectives

Revision Document ID22842

Date Revision 17 Oct

2017 Reviewed 17 Oct 2017

Need Risks and Expectations of **External Parties** Viamed

Revision Document ID165559 Date Revision 21 Oct 2024 Reviewed 21 Oct

2024

Viamed Certification ISO 13485:2016

MD78787

Revision Document ID176874

Date Revision 20 Feb 2025 Reviewed 26 Jun 2025

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)

Top Level Document:

Viamed ISO 13485:2016 Scope

Revision Document

ID168096

Date Revision 18 Nov 2024 Reviewed 02 Oct

2025

Top Level Document:

VOP 01

Documentation and Records, Control, Creation, Storage, Retrieval, Revision **Control and Online** Records

Revision Document ID120321

Date Revision 01 Jun 2023 Reviewed 25 Jun

2025 Audit 10

Documentation **Control Viamed**

Revision Document

Process: 7723

Audit 10b Process Verification Viamed

24 Aug 2016

Process: 41

Responsibility Allocation :

Documentation Control 16 Feb 2016

Process: 9

Distribution Of Faxes 16 Feb 2016

Process: 10

Distribution Of Emails 16 Feb 2016

Process: 8025

Check We Do Not Require A EU European Representatives 09 Mar

2023

undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken Documentation by the organization can include manufacturer, authorized representative, importer

ID159363 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 10 **Control VST Revision Document** ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

2024

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

4.1.2

or distributor.

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 ID167103 Date Revision 06 Nov 2024 Reviewed 06 Nov

Top Level Document: VOP 21 Risk, Risk Management and Risk Analysis

Revision Document ID177830

Date Revision 03 Mar 2025 Reviewed 03 Mar 2025

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 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

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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

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Date Revision 12 Oct 2011 Reviewed 12 Oct 2011

Audit 20 Process verification to **Managment Viamed**

Revision Document ID159389

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

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 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

Top Level Document:

VOP 13 Process Monitoring, System

Reviews, Audits, **Management Reviews**

Analysis Data PMS Post Market

Revision Document ID135771

Date Revision 28 Nov 2023 Reviewed 26 Jun

2025

availability of resources Explanation Employee Process: 7714

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

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

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

and compliance with applicable regulatory requirements (see 4.2.5).

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

ID85362

Date Revision 22 Mar

2022 Reviewed 22 Mar

2022

Employee Roles Individual Processes

. . .

Revision Document

ID20127

Date Revision 16 May

2017 Reviewed 16 May

2017

Audit 20 Process

verification to

Managment Viamed

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

Audit 22 Post Market Survellance

Viamed 24 Aug 2016

Process: 7733

Audit 23 Analysis Of Data Viamed 24

Aug 2016

Process: 26

Company Resources 16 Feb 2016

Process: 8025

Check We Do Not Require A EU

European Representatives 09 Mar

2023

Process: 8028

Viamed Shopify Sales Report Export

11 Apr 2023

Revision Document ID159389 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 **Audit 18 Management Review Viamed** Revision Document ID159471 Date Revision 13 Aug 2024 Reviewed 13 Aug

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 Revision Document 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

c) controlled in

and applicable

regulatory

management system

accordance with the

requirements of this International Standard Top Level Document: **VOP 01**

2024

Documentation and Records, Control, Creation, Storage, Retrieval, Revision **Control and Online** Records Revision Document

ID120321 Date Revision 01 Jun 2023 Reviewed 25 Jun 2025

Audit 20 Process verification to **Managment Viamed**

ID159389

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

Audit 18 Management **Review Viamed**

Revision Document ID159471

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

Issues Overview

Revision Document ID23112

Date Revision 22 Oct

Process: 7725

Audit 12 CE Files Viamed 24 Aug 2016

Process: 7730

Audit 20 Process Verification To Managment Viamed 24 Aug 2016

Process: 7878

Review Possible Upcoming Regulation

Changes 22 Oct 2017

Process: 8025

Check We Do Not Require A EU European Representatives 09 Mar

2023

Process: 8077

Download HMRC Reports 18 Jun 2024

requirements.

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

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

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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

VM3COP24.02 Document Change Performing a Risk Assessment

Revision Document ID75310

Date Revision 17 Nov 2021 Reviewed 17 Nov 2021

VM3COP24.01 Definitions of Risk

Revision Document ID75525 Date Revision 19 Nov 2021 Reviewed 19 Nov

2021 Neviewed 2

VM3COP24.00 Viamed Overall Risk Analysis Program Risk Register

Revision Document ID47771

Date Revision 12 Nov 2020 Reviewed 17 Dec 2024

4.1.5 For each quality Top Level Document: VOP 05 Supplier Process: 7717

Audit 05 Purchasing Suppliers Viamed

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.

Control, Supplier
Review, Purchase
Orders, Supplier
Returns and Rejection
Revision Document
ID200924
**Date Revision 30 Oct
2025 Reviewed 30 Oct
2025
Audit 05 Purchasing

Revision Document ID159433 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

suppliers Viamed

24 Aug 2016 **Process: 7199**

Non Conformities Review Viamed 09

Mar 2016

Process: 8025

Check We Do Not Require A EU European Representatives 09 Mar

2023

4.1.6

For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be

Top Level Document: VOP 27 Software

Validation

Revision Document

ID91486

Date Revision 10 Jun

2022 Reviewed 10 Jun

2022

Top Level Document:
Audit 27 Software
Validation Viamed
Revision Document

ID156701

Process: 7850

Software Validation Scan Incorrect

Product 01 Oct 2017

Process: 7851

Software Validation Scan Un-QA

Product To Order 01 Oct 2017

Process: 7852

Software Validation Expired Stock 01

Oct 2017

Process: 7853

Software Validation Non Sell Able

Shelf 01 Oct 2017

Process: 7854

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 2017 revalidation shall be proportionate to the risk associated with the Revision Document use of the software. Records of such activities shall be maintained (see 4.2.5).

Date Revision 12 Jul 2024 Reviewed 12 Jul 2024

Log

Revision Document ID20136

Date Revision 16 May 2017 Reviewed 16 May

Validation of Intrastats

ID20140

Date Revision 16 May 2017 Reviewed 16 May 2017

Software Validation In Production List 01 Oct 2017

Process: 7855

Intrastats Amendment 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

Process: 8083

Software Validation SRS To Nonconformance 31 Oct 2024

Process: 8085

Stock Figure - Correct Xero To

Intrastats 16 Dec 2024

4.2 Documentation

requirements

Top Level Document: VOP 01

Documentation and Records, Control, Creation, Storage, Retrieval. Revision **Control and Online** Records

Revision Document ID120321

Date Revision 01 Jun 2023 Reviewed 25 Jun 2025

Process: 8096

Review Contracts Advance Renewal 17 Iun 2025

Audit 10 Documentation **Control Viamed**

Revision Document ID159363 Date Revision 13 Aug

2024 Reviewed 13 Aug 2024

Audit 10

Documentation

Control VST

Revision Document

ID159361

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

4.2.1

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 VOP 01

required by this

d) documents,

including records, determined by the

organization to be

necessary to ensure the Revision Document

effective planning,

operation, and control

of its processes;

e) other documentation specified by applicable

regulatory

requirements.

Top Level Document:

VM3COP00.00

VOP00.00 Viamed

Quality Statement

policy and objectives

Revision Document

ID164833

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2024 Reviewed 04 Nov

2024

Top Level Document:

Documentation and

International Standard; Records, Control,

Creation, Storage,

Retrieval, Revision

Control and Online

Records

ID120321

Date Revision 01 Jun

2023 Reviewed 25 Jun

2025

Explaination Quality

Objectives

Revision Document

ID18483

Date Revision 18 Jan

Process: 23

Company Objectives 16 Feb 2016

Process: 22

Company Policys 16 Feb 2016

Process: 23

Company Objectives 16 Feb 2016

Process: 7730

Audit 20 Process Verification To

Managment Viamed 24 Aug 2016

Process: 7723

Audit 10b Process Verification Viamed

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

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2017 Reviewed 18 Jan

2017

Roles and Titles Revision Document

ID22144

Date Revision 20 Sep

2017 Reviewed 20 Sep

2017

Audit 20 Process

verification to

Managment Viamed

Revision Document

ID159389

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 10

Documentation

Control Viamed

Revision Document

ID159363

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

VM3COP00.01

Company objectives

Revision Document

ID22842

Date Revision 17 Oct

2017 Reviewed 17 Oct

2017

Audit 10

Documentation

Control VST

Revision Document

ID159361

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

communication 09 Mar 2016

Process: 7057

Explanation Employee 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 Viamed 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

Process: 8029

Send Intercompany Invoices To Jean

12 Apr 2023

4.2.2

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 ID167103 processes of the quality management system. The quality manual shall outline the structure of the

documentation used in

the quality

Top Level Document:

VM3COP02.01

Exclusions to Viamed

ISO13485:2016

boundaries of ISO

Revision Document ID74571

Date Revision 10 Nov 2021 Reviewed 01 Aug 2025

Top Level Document:

VM3COP02.02 Viamed

Company

Responsibilitys

organisation chart

structure

Revision Document

Date Revision 06 Nov 2024 Reviewed 06 Nov

2024

Top Level Document: Viamed ISO

13485:2016 Scope

Revision Document

Process: 7723

Audit 10b Process Verification Viamed

24 Aug 2016

Process: 7730

Audit 20 Process Verification To Managment Viamed 24 Aug 2016

management system.

ID168096

Date Revision 18 Nov 2024 Reviewed 02 Oct

2025

Structure of the documentation used in the quality management system

Revision Document

ID151811

Date Revision 21 May 2024 Reviewed 21 May

2024

Audit 20 Process verification to

Managment Viamed

Revision Document

ID159389

Date Revision 13 Aug 2024 Reviewed 13 Aug

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Audit 10

Documentation

Control Viamed

Revision Document

ID159363

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

Audit 10

Documentation

Control VST

Revision Document

ID159361

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

4.2.3

For each medical device VOP 17 Design type or medical device family, the organization Development shall establish and maintain one or more files either

Top Level Document:

Research and

Revision Document ID25632

Date Revision 19 Mar

Process: 7716

Audit 03 Design Control Viamed 24

Aug 2016

Process: 7723

Audit 10b Process Verification Viamed

24 Aug 2016

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 Revision Document 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. Medical device file **Documentation**

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 Viamed**

ID173558 Date Revision 22 Jan 2025 Reviewed 26 Jun

2025

4.2.4Documents required by the quality management system

shall be controlled.

requirements

Top Level Document: VOP 01 Documentation and Records, Control, Creation, Storage,

Process: 7722

Audit 10 Documentation Control

Viamed 24 Aug 2016

Process: 8032

Review Contact Documentation 22 Aug

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Records are a special type of document and shall be controlled according Revision Document 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; ID21322 b) review, update as necessary and reapprove documents; c) ensure that the current revision status of and changes to documents are identified: d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality Revision Document management system, are identified and their distribution controlled; g) prevent deterioration 2011 or loss of documents; h) prevent the unintended use of obsolete documents and apply suitable

Retrieval, Revision **Control and Online** Records ID120321 Date Revision 01 Jun 2023 Reviewed 25 Jun 2025 **Explanation Control** of documents Revision Document Date Revision 06 Aug 2017 Reviewed 06 Aug 2017 DO NOT USE VM3COP01 Document Updates / Amendment control Revision Document ID22201 Date Revision 23 Sep 2017 Reviewed 23 Sep 2017 Audit 10 Documentation **Control Viamed** Revision Document ID159363 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 DO NOT USE VM3COP14 Documentation ID9276 Date Revision 18 Oct 2011 Reviewed 18 Oct Audit 23 Analysis of Data Viamed Revision Document

2023

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ID158752

Date Revision 06 Aug

identification to them. The organization shall ensure that changes to documents are reviewed and approved out in the Field 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 Control of documents Documentation requirements

2024 Reviewed 06 Aug 2024 VM3COP10.02 Product Recall locate products Revision Document ID74788 Date Revision 12 Nov 2021 Reviewed 12 Nov 2021 Audit 10 Documentation **Control VST Revision Document** ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

4.2.5 Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality **Top Level Document: VOP 01** Documentation and Records, Control, Creation, Storage, Retrieval, Revision **Control and Online**

Process: 7722

Audit 10 Documentation Control

Viamed 24 Aug 2016

Process: 7725

Audit 12 CE Files Viamed 24 Aug 2016

Process: 8027

Update Pricing For Viamed Shopify 11

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management system. The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable. The organization shall retain the records for at Date Revision 22 Dec 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. **Control** of records Documentation requirements

Records Revision Document ID120321 Date Revision 01 Jun 2023 Reviewed 25 Jun 2025 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 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

Apr 2023

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Audit 10

Documentation

Control Viamed

Revision Document

ID159363

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Audit 10

Documentation

Control VST

Revision Document

ID159361

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

5 Management commitment

5.1

Top management shall provide evidence of its

commitment to the development and

implementation of

the quality

management system

and maintenance of its

effectiveness by:

a) communicating to the organization the

importance of meeting

customer as well as

applicable

regulatory

requirements;

b) establishing the

quality policy;

c) ensuring that quality

objectives are

established;

d) conducting

management reviews;

e) ensuring the

availability of

resources.

Top Level Document:

VOP 02 Personnel and Responsibility , Staff

and Staffing Issues,

Training, Roles and

Tasks

Revision Document

ID151817

Date Revision 21 May

2024 Reviewed 21 May

2024

Top Level Document:

VOP 18 Maintenance

Building, Fabric and

Infrastructure

Revision Document

ID119029

Date Revision 15 May

2023 Reviewed 15 May

2023

Top Level Document:
Viamed Top Level

Quality Objectives

Viamed Objectives

Revision Document

ID185333

Date Revision 14 May

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

Process: 7686

Thorough Checking Of Awaiting

Action Tray - Priority 8s 21 Apr 2016

Process: 7919

Send Debtors Overview To Derek 06

Dec 2018

Process: 8080

Review Back To Stock Report On

Shopify 10 Sep 2024

Management commitment

2025 Reviewed 14 May 2025

Top Level Document: VM3COP00.00

VM3COP00.00 VOP00.00 Viamed Quality Statement policy and objectives

Revision Document

ID164833

Date Revision 14 Oct 2024 Reviewed 04 Nov

2024

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 Viamed

Process: 8094

Meeting With DL 16 May 2025

Revision Document ID159389

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

Explaination 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 Viamed

Revision Document ID159471

	Date Revision 13 Aug 2024 Reviewed 13 Aug	
	2024	
5.2	Top Level Document:	Process: 7
Top management shall	VOP 03 Contract	Responsibility Allocation : Checking Of
ensure that customer	Review, Enquires,	Sales Orders 16 Feb 2016
requirements and	Office Processes	Process: 11
applicable regulatory	Revision Document	Distribution Of Post 16 Feb 2016
requirements are	ID77875	Process: 5882
determined and met.	Date Revision 15 Dec	Responsibility Allocation : Send Post
	2021 Reviewed 21 May	To Humanmed 24 Feb 2016
Customer focus	2024	Process: 2
	Top Level Document:	Answering Telephones 16 Feb 2016
	Audit 02 Contract	Process: 7715
	Review and Sales	Audit 02 Contract Review Viamed 24
	Order Processing	Aug 2016
	Viamed	Process: 7743
	Revision Document	Customer Complaints Paper File 26
	ID163469	Sep 2016
	Date Revision 27 Sep	Process: 7716
	2024 Reviewed 27 Sep	Audit 03 Design Control Viamed 24
	2024	Aug 2016
	Top Level Document:	Process: 7696
	VOP 19 Feedback	Send VIAMED Delivery Notifications
	Customer Complaints	28 Apr 2016
	Vigilance and	Process: 6898
	Notifications Viamed	GHX Web Pricing 09 Mar 2016
	Ltd	Process: 19
	Revision Document	Maintaining Leaflet Stocks 16 Feb 2016
	ID132118	Process: 14
	Date Revision 18 Oct	Fax Paper 16 Feb 2016
	2023 Reviewed 18 Oct	Process: 15
	2023	Filing and Archiving 16 Feb 2016
	Top Level Document:	Process: 10
	VOP 07 Stock Control,	Distribution Of Emails 16 Feb 2016
	Handling, Control of	Process: 9
	Labelling, Storage,	Distribution Of Faxes 16 Feb 2016
	Movement	Process: 7996
	Revision Document	Verification Repairs Older Repairs 07
	ID137933	Feb 2022
	Date Revision 27 Dec	Process: 7934
	2023 Reviewed 27 Dec	Test Website Questions 02 May 2019
	2023	Process: 8075
	Audit 16 Sales and	Tenders Review UK 14 Feb 2024

	Name of the second	D
	Marketing Viamed	Process: 8076
	Revision Document	Medica Review 21 Feb 2024
	ID159461	Process: 7968
	Date Revision 13 Aug	Shred CC Slips 06 Aug 2021
	2024 Reviewed 13 Aug	
	2024	
5.3	Top Level Document:	Process: 23
Top management shall	VM3COP00.00	Company Objectives 16 Feb 2016
ensure that the quality	VOP00.00 Viamed	Process: 22
policy:	Quality Statement	Company Policys 16 Feb 2016
a) is applicable to the	policy and objectives	Process: 23
purpose of the	Revision Document	Company Objectives 16 Feb 2016
organization;	ID164833	Process: 7723
b) includes a	Date Revision 14 Oct	Audit 10b Process Verification Viamed
commitment to comply	2024 Reviewed 04 Nov	24 Aug 2016
with requirements and	2024	Process: 7833
to maintain the	VM3COP00.01	Importance Of Effective Quality
effectiveness of the	Company objectives	Management 20 Sep 2017
quality management	Revision Document	Process: 7828
system;	ID22842	Review The Quality Policy Viamed 16
c) provides a	Date Revision 17 Oct	Sep 2017
framework for	2017 Reviewed 17 Oct	Process: 7827
establishing and	2017	Review The Quality Policy VST 16 Sep
reviewing quality	Audit 18 Management	2017
objectives;	Review Viamed	
d) is communicated and		
understood within the	ID159471	
organization;	Date Revision 13 Aug	
e) is reviewed for	2024 Reviewed 13 Aug	
continuing suitability.	2024 Reviewed 15 Hag	
Quality policy	Audit 20 Process	
Quality policy	verification to	
	Managment Viamed	
	Revision Document	
	ID159389	
	Date Revision 13 Aug	
	2024 Reviewed 13 Aug	
	2024 Reviewed 13 Mag	
5.4		
Planning		
5.4.1	Top Level Document:	Process: 7730
Top management shall	Viamed Top Level	Audit 20 Process Verification To
ensure that quality	Quality Objectives	Managment Viamed 24 Aug 2016
objectives, including	Viamed Objectives	Process: 7830

those needed to meet applicable regulatory requirements and requirements for product, are established **Top Level Document:** at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Quality objectives

Revision Document ID185333

Date Revision 14 May 2025 Reviewed 14 May

2025

VOP 07 Stock Control, Handling, Control of Labelling, Storage,

Movement

Revision Document

ID137933

Date Revision 27 Dec 2023 Reviewed 27 Dec

2023

Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection

Revision Document

ID181426

Date Revision 02 Apr 2025 Reviewed 02 Apr

2025

VM3COP18 Post Market Surveilance

Revision Document ID75985

Date Revision 24 Nov 2021 Reviewed 24 Nov 2021

Explanation Employee Roles and Titles

Revision Document

ID22144

Date Revision 20 Sep 2017 Reviewed 20 Sep

2017

Explaination Quality

Objectives

Revision Document

ID18483

Date Revision 18 Jan 2017 Reviewed 18 Jan Review Q.A. Failures Report 18 Sep

2017

Process: 26

Company Resources 16 Feb 2016

Process: 5877

Review Company Data 17 Feb 2016

Audit 20 Process
verification to
Managment Viamed
Revision Document
ID159389
Date Revision 13 Aug
2024 Reviewed 13 Aug
2024

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

ID167103 Date Revision 06 Nov 2024 Reviewed 06 Nov 2024

Top Level Document: Viamed Top Level Quality Objectives Viamed Objectives

Revision Document ID185333 Date Revision 14 May

2025 Reviewed 14 May 2025

Top Level Document:
VM3COP00.00
VOP00.00 Viamed
Quality Statement
policy and objectives

Revision Document ID164833

Date Revision 14 Oct 2024 Reviewed 04 Nov 2024

Top Level Document: VOP 21 Risk, Risk Management and Risk Analysis

Revision Document

Process: 11

Distribution Of Post 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

ID177830

Date Revision 03 Mar 2025 Reviewed 03 Mar 2025

Explanation Employee Roles and Titles

Revision Document

ID22144 Date Revision 20 Sep 2017 Reviewed 20 Sep 2017

Explaination Quality Objectives

Revision Document ID18483

Date Revision 18 Jan 2017 Reviewed 18 Jan 2017

Explanation Control of documents

Revision Document ID21322

Date Revision 06 Aug 2017 Reviewed 06 Aug 2017

Route to Medical device files

Revision Document ID18495

Date Revision 18 Jan 2017 Reviewed 18 Jan 2017

VM3COP20.01 Post In Distributing the Post

Revision Document ID103501

Date Revision 14 Nov 2022 Reviewed 14 Nov 2022

Audit 20 Process verification to Managment Viamed

Revision Document ID159389

Date Revision 13 Aug

 $33 ext{ of } 158$ 10/11/2025, 09:48

	2024 Reviewed 13 Aug 2024 VM3COP00.01 Company objectives	
	Revision Document ID22842 Date Revision 17 Oct 2017 Reviewed 17 Oct	
5.5 Responsibility, authority and	Top Level Document: VOP 02 Personnel and Responsibility , Staff	
communication	and Staffing Issues, Training, Roles and Tasks	
	Revision Document ID151817 Date Revision 21 May	
	2024 Reviewed 21 May 2024 Top Level Document:	
	QC 44 MHRA / CMDCAS Risk Assessment Initial	
	Assessment form Revision Document ID75549 Date Revision 19 Nov 2021 Reviewed 19 Nov	
	2021 Top Level Document: VOP 19 Feedback Customer Complaints	
	Vigilance and Notifications Viamed Ltd	
	Revision Document ID132118 Date Revision 18 Oct 2023 Reviewed 18 Oct 2023	
5.5.1 Top management shall ensure that	Top Level Document: VOP 02 Personnel and Responsibility , Staff	Process: 7720 Audit 08 Training Viamed 24 Aug 2016 Process: 7730

responsibilities and authorities are defined, documented and communicated within the organization. Top management shall document the interrelation of all personnel who manage, Top Level Document: perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks. Responsibility and

authority

and Staffing Issues, Training, Roles and Tasks

Revision Document ID151817

Date Revision 21 May

2024 Reviewed 21 May 2024

VM3COP02.02 Viamed Company

Responsibilitys organisation chart structure

Revision Document ID167103

Date Revision 06 Nov 2024 Reviewed 06 Nov 2024

Explanation Employee Roles and Titles

Revision Document ID22144

Date Revision 20 Sep 2017 Reviewed 20 Sep

2017

VM3COP02

Organisation

Responsibilities

Viamed

Revision Document

ID17423

Date Revision 07 Sep 2016 Reviewed 07 Sep 2016

Chart 01 System and Documentation

Revision Document

ID8675

Date Revision 12 Oct 2011 Reviewed 12 Oct

2011

Chart 02 Resource Management

Revision Document

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

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 Viamed

Revision Document ID162725 Date Revision 19 Sep

2024 Reviewed 19 Sep 2024

Audit 20 Process verification to **Managment Viamed** Revision Document ID159389 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 19 Health and Safety, Working Conditions and **Building Fabric Issues** Viamed **Revision Document** ID159483 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

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 2024 regulatory requirements and quality

management system

Top Level Document: VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID151817 Date Revision 21 May

2024 Reviewed 21 May 2024

Top Level Document: VM3COP02.02 VST Company Responsibilitys organisation chart

Revision Document ID29373 Date Revision 23 Apr

structure

2019 Reviewed 25 Jan

Top Level Document: VM3COP02.02 Viamed Company Responsibilitys Process: 7730

Audit 20 Process Verification To Managment Viamed 24 Aug 2016

Process: 7833

Importance Of Effective Quality Management 20 Sep 2017

requirements	organisation chart
throughout the	structure
organization.	Revision Document
Management	ID167103
representative	Date Revision 06 Nov
	2024 Reviewed 06 Nov
	2024
	Explanation Employee
	Roles and Titles
	Revision Document
	ID22144
	Date Revision 20 Sep
	2017 Reviewed 20 Sep
	2017
	Audit 20 Process
	verification to
	Managment Viamed
	Revision Document
	ID159389
	Date Revision 13 Aug
	2024 Reviewed 13 Aug
	2024
	VM3COP02
	Organisation
	Responsibilities
	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
5.5.3	VM3COP27.01

Top management shall ensure that appropriate communication processes are established within vimaco Search Search Issues Revision ID6657

VM3COP27.01
Searching Intrastats
Issues
Revision Document
ID6657
Date Revision 02 Nov

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

Internal

Internal communication 2009 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	Top Level Document:	Process: 7846
The organization shall	VOP 13 Process	ISO System Management Review
document procedures	Monitoring, System	Viamed 26 Sep 2017
for management	Reviews, Audits,	Process: 27
review. Top	Management Reviews	Management Reviews And Quality
management shall	Analysis Data PMS	Audits 16 Feb 2016
review	Post Market	Process: 7070
the organization's	Revision Document	Management Review 09 Mar 2016
quality management	ID135771	
system at documented	Date Revision 28 Nov	
planned intervals to	2023 Reviewed 26 Jun	
ensure its	2025	
continuing suitability,	How to Hold Intrastat	
adequacy, and	Meetings	
effectiveness. The	Revision Document	
review shall include	ID8928	
assessing opportunities	Date Revision 18 Oct	
for	2011 Reviewed 18 Oct	
improvement and the	2011	
need for changes to the	Audit 18 Management	
quality management	Review Viamed	
system, including the	Revision Document	
quality policy	ID159471	
and quality objectives.	Date Revision 13 Aug	
Records from	2024 Reviewed 13 Aug	
management reviews	2024	
shall be maintained	Management Review	
General	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	
	Audit 10	
	Documentation	
	Control Viamed	
	Revision Document	

ID159363

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Audit 10

Documentation

Control VST

Revision Document

ID159361

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

5.6.2

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

revised regulatory

requirements. General

Review input

Top Level Document:

VOP 19 Feedback

Customer Complaints

Vigilance and

Notifications Viamed

Ltd

Revision Document

ID132118

Date Revision 18 Oct

2023 Reviewed 18 Oct

2023

Top Level Document:

VM3COP02.02 Viamed

Company

Responsibilitys

organisation chart

structure

Revision Document

ID167103

Date Revision 06 Nov

2024 Reviewed 06 Nov

2024

Top Level Document:

VOP 13 Process

Monitoring, System

Reviews, Audits,

Management Reviews

Analysis Data PMS

Post Market

Revision Document

ID135771

Date Revision 28 Nov

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

Viamed 26 Sep 2017

Process: 7848

Review ISO Scopes 27 Sep 2017

Process: 7849

100033.7043

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

2023 Reviewed 26 Jun 2025

Chart 27 Customer
Complaints Chart 27

Revision Document

ID8700

Date Revision 12 Oct 2011 Reviewed 12 Oct

2011

VM3COP18 Post

Market Surveilance

Revision Document

ID75985

Date Revision 24 Nov 2021 Reviewed 24 Nov

2021

How to Hold Intrastat Meetings

Revision Document

ID8928

Date Revision 18 Oct

2011 Reviewed 18 Oct

2011

Audit 21 Audit of

Audit Viamed

Revision Document

ID159485

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Audit 22 Post Market Survellance Viamed

Revision Document

ID186382

Date Revision 23 May

2025 Reviewed 23 May

2025

Audit 23 Analysis of

Data Viamed

Revision Document

ID158752

Date Revision 06 Aug

2024 Reviewed 06 Aug

2024

Audit 18 Management

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

Process: 8014

Review VIAMED Product Feedback

Positive 25 Jul 2022

Process: 8016

Review VIAMED Customer Feedback

Positive 25 Jul 2022

Process: 8089

Review Any Outstanding QC 21 Forms

To Sign Off 07 Feb 2025

Review Viamed

Revision Document ID159471

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

Viamed Management **Review Blank Minutes** 20xx

Revision Document ID126137

Date Revision 04 Aug 2023 Reviewed 04 Aug 2023

QC 21 Non

Conformance Form

Revision Document ID74728

Date Revision 11 Nov 2021 Reviewed 28 Jul 2025

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 2021 Reviewed 19 Nov to maintain the suitability, adequacy, and effectiveness of the Revision Document 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

Top Level Document:

QC 44 MHRA / **CMDCAS Risk**

Assessment Initial Assessment form

Revision Document

ID75549

Date Revision 19 Nov

2021

Issues Overview

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

Process: 7730

Audit 20 Process Verification To Managment Viamed 24 Aug 2016

requirements;	2009
d) resource needs.	Management Review
Review output	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
	ID19803
	Date Revision 05 May
	2017 Reviewed 05 May
	2017
	Audit 20 Process
	verification to
	Managment Viamed
	Revision Document
	ID159389
	Date Revision 13 Aug
	2024 Reviewed 13 Aug
	2024
	Audit 18 Management
	Review Viamed
	Revision Document
	ID159471
	Date Revision 13 Aug
	2024 Reviewed 13 Aug
	2024

6 Resource management

6		
Resource		
management		
6.1	Top Level Document:	Process: 7723
The organization shall	VOP 02 Personnel and	Audit 10b Process Verification Viamed
determine and provide	Responsibility , Staff	24 Aug 2016

the resources needed to: a) implement the quality management system and to maintain ID151817 its effectiveness; b) meet applicable regulatory and customer requirements. Audit 20 Process Provision of resources

and Staffing Issues, Training, Roles and Tasks Revision Document Date Revision 21 May 2024 Reviewed 21 May 2024 verification to **Managment Viamed Revision Document** ID159389

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Process: 7730

Audit 20 Process Verification To Managment 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

necessary competence;

Top Level Document: VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training, Roles and Tasks Revision Document ID151817 Date Revision 21 May 2024 Reviewed 21 May 2024

Top Level Document: VOP 12 Training Revision Document

ID166222 Date Revision 25 Oct

2024 Reviewed 25 Oct 2024

Explanation Employee Roles and Titles Revision Document

ID22144

Date Revision 20 Sep 2017 Reviewed 20 Sep

2017

Audit 08 Training, achieve or maintain the Competence and **Human Resources** Process: 7720

Audit 08 Training Viamed 24 Aug 2016

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 Revision Document 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

6.3

document the

to achieve

requirements for the

infrastructure needed

conformity to product

requirements, prevent

product mix-up and

handling of product.

and associated utilities;

b) process equipment

c) supporting services

(both hardware and

ensure orderly

as appropriate:

software);

Viamed Revision Document ID162725 Date Revision 19 Sep 2024 Audit 19 Health and Safety, Working

2024 Reviewed 19 Sep Conditions and **Building Fabric Issues** Viamed ID159483 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

Top Level Document: The organization shall

VOP 06 Measurement Control Viamed VST,

Calibration, QA Stock

Revision Document ID168580

Date Revision 22 Nov

2024 Reviewed 22 Nov

2024

Top Level Document:

VOP 18 Maintenance

Infrastructure includes, **Building, Fabric and** Infrastructure

a) buildings, workspace Revision Document

ID119029

Date Revision 15 May

2023 Reviewed 15 May 2023

Top Level Document:

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

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(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 maintenance shall be maintained Infrastructure

VOP 16 Health and Safety, Company Personnel Manual Revision Document

ID31032 Date Revision 30 Sep 2019 Reviewed 30 Sep

2019

Top Level Document: VOP 11 Equipment

Control, Office,

Warehouse, Pcs and

Equipment

Revision Document

ID174218

Date Revision 29 Jan 2025 Reviewed 29 Jan

2025

DO NOT USE

VM3COP11 Calibration Process: 5921

Revision Document

ID8713

Date Revision 12 Oct 2011 Reviewed 12 Oct

2011

HSE Fire / Exit Escape

route Ground Floor plans

Revision Document

ID127734

Date Revision 25 Aug 2023 Reviewed 04 Nov

2024

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

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

Process: 5919

Check Out Side Drain 05 Mar 2016

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

47 of 158

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

ID127738

Date Revision 25 Aug 2023 Reviewed 04 Nov

2024

HSE Fire / Exit Escape

route Ghyll House floor plans

Revision Document

TO TOO

ID95898

Date Revision 04 Aug 2022 Reviewed 04 Nov

2024

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

ID82517

Date Revision 15 Feb

Sep 2017

Process: 45

Responsibility Allocation : Main

Server Status 16 Feb 2016

Process: 48

Responsibility Allocation : Internet 16

Feb 2016 **Process: 52**

0.6. 11.6. ...

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 Incorrect

Product 01 Oct 2017

Process: 7851

Software Validation Scan Un-QA

Product To Order 01 Oct 2017

Process: 7852

Software Validation Expired Stock 01

Oct 2017

Process: 7853

Software Validation Non Sell Able

Shelf 01 Oct 2017

Process: 7854

Software Validation In Production List

01 Oct 2017

Process: 7855

Software Validation - Production Lists

01 Oct 2017

 $48 ext{ of } 158 ext{ } 10/11/2025, 09:48$

2022 Reviewed 15 Feb

2024

VM3COP20.35 Ups

Calculator

Revision Document

ID88671

Date Revision 05 May

2022 Reviewed 05 May

2022

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 Process: 5906

Roles and Titles

Revision Document

ID22144

Date Revision 20 Sep

2017 Reviewed 20 Sep

2017

Audit 07 Handling and

Storage Viamed

Revision Document

ID184932

Date Revision 09 May

2025 Reviewed 09 May

2025

Audit 15 Production

Viamed

Revision Document

ID191692

Date Revision 21 Jul

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: 7832

Cleardown Emailed Invoices 20 Sep

2017

Process: 7755

Fast Hosts Invoice 08 Dec 2016

Process: 7739

Intrastats Amendment Log 12 Sep

2016

Process: 5853

Vacuuming Of The Office, Hall And

Meeting Room 17 Feb 2016

Process: 5878

Empty Office Bins 18 Feb 2016

Empty Paper Bins 03 Mar 2016

Process: 5910

Clean Duckets 03 Mar 2016

Process: 7961

R D Room - Tidy, Empty Bins, Remove Cups. Caution Around Oxygen Supply

05 Oct 2020

Process: 7896

Tree In Car Park 22 Dec 2017

Process: 7864

ESD Work Stations 07 Oct 2017

Process: 46

Responsibility Allocation : Backup

Server Status 16 Feb 2016

Process: 44

Secure Socket Level Certificate 16 Feb

2016

Process: 49

2025 Reviewed 21 Jul 2025 Audit 19 Health and Safety, Working Conditions and **Building Fabric Issues** Viamed Revision Document

ID159483 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

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: 53

Emails 16 Feb 2016

6.4 Work environment and contamination control

Top Level Document: VM3COP27.51 Incoming / Goods in Contamination Control Revision Document ID74855 Date Revision 12 Nov 2021 Reviewed 12 Nov

6.4.1

The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document

Top Level Document: VOP 18 Maintenance

Building, Fabric and Infrastructure

Revision Document

ID119029

Date Revision 15 May 2023 Reviewed 15 May

2023

2021

Top Level Document: VOP 16 Health and

Safety, Company Personnel Manual

Revision Document

ID31032

Date Revision 30 Sep

2019 Reviewed 30 Sep

2019

CPM 15 Disciplinary

Procedures

Revision Document

ID142873

Process: 7719

Audit 07 Handling And Storage

Viamed 24 Aug 2016

Process: 7720

Audit 08 Training Viamed 24 Aug 2016

Process: 7729

Audit 19 Health And Saftey Viamed 24

Aug 2016 Process: 56

Warehouse Outside Heating Guard 17

Feb 2016

Process: 5919

Check Out Side Drain 05 Mar 2016

Process: 5921

Clearing Water Downstairs 05 Mar

2016

Process: 7120

General Maintenance Requirements

09 Mar 2016

Process: 7742

Boiler Check 26 Sep 2016

Process: 7756

requirements for health, cleanliness and clothing of personnel if 2024 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

Date Revision 21 Feb 2024 Reviewed 21 Feb

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

Storage Viamed

Revision Document

ID184932

Date Revision 09 May 2025 Reviewed 09 May

2025

Audit 08 Training, Competence and

Human Resources

Viamed

Revision Document

ID162725

Date Revision 19 Sep

2024 Reviewed 19 Sep

2024

Audit 19 Health and Safety, Working Conditions and **Building Fabric Issues**

Viamed

Revision Document

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: 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

Audit 07 Handling and 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

ID159483 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

6.4.2

As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes. Contamination

control

Top Level Document:

VM3COP02.01

Exclusions to Viamed

ISO13485:2016

boundaries of ISO

Revision Document

ID74571

Date Revision 10 Nov

2021 Reviewed 01 Aug

2025

Top Level Document:

VOP 20 Goods in

Purchases, Returns, Repairs, Inspection /

Rejection

Revision Document

ID181426

Date Revision 02 Apr

2025 Reviewed 02 Apr

2025

Top Level Document: VOP 09 Repairs and

Servicing

Servicing

Revision Document

ID137919

Date Revision 27 Dec

2023 Reviewed 27 Dec

2023

Top Level Document:

VOP 05 Supplier

Control, Supplier

Review, Purchase

Orders, Supplier

Returns and Rejection

Revision Document

ID200924

**Date Revision 30 Oct 2025 Reviewed 30 Oct 2025

Top Level Document:

Process: 39

Enviromental Policy Document

Review 16 Feb 2016

Process: 7719

Audit 07 Handling And Storage

Viamed 24 Aug 2016

Process: 7714

Audit 01 Picking Packing Viamed 24

Aug 2016

Process: 7721

Audit 09 Goods Inward And Product

Identity Viamed 24 Aug 2016

VM3COP27.51 Incoming / Goods in Contamination Control **Revision Document** ID74855 Date Revision 12 Nov 2021 Reviewed 12 Nov 2021 **Audit 09 Goods Inward and Product Identity Viamed** Revision Document ID166168 Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

7 Product realization

Product realization 7.1 **Top Level Document:** Process: 7732 VM3COP27.11 Audit 22 Post Market Survellance The organization shall plan and develop the Performing a Viamed 24 Aug 2016 processes needed for **Technical File PMS** Process: 7716 product realization. Audit 03 Design Control Viamed 24 and risk assessment Planning of **Revision Document** Aug 2016 product realization ID75465 shall be consistent with Date Revision 18 Nov 2021 Reviewed 18 Nov the requirements of the other processes of the 2021 quality **Top Level Document:** management system. VOP 08 Production, The organization shall Reworks, New document one or more **Production** Revision Document processes for risk ID31072 management in product realization. Date Revision 30 Sep Records of risk 2019 Reviewed 30 Sep management activities 2019 shall be maintained VM3COP24.00 Viamed (see 4.2.5). **Overall Risk Analysis** Program Risk Register

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 2015 product, including infrastructure and work environment; c) required verification, ID186382 validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. **NOTE Further** information can be found in ISO 14971.

Revision Document ID47771 Date Revision 12 Nov 2020 Reviewed 17 Dec 2024 VM3COP27.12 Clinical **Evaluation Risk** assessment Technical Files **Revision Document** ID15453 Date Revision 11 Aug 2015 Reviewed 11 Aug Audit 22 Post Market Survellance Viamed Revision Document Date Revision 23 May 2025 Reviewed 23 May 2025 Audit 03 Design **Control Viamed** Revision Document ID173558 Date Revision 22 Jan 2025 Reviewed 26 Jun 2025 Audit 07 Handling and Storage Viamed Revision Document ID184932 Date Revision 09 May 2025 Reviewed 09 May 2025 **Audit 09 Goods Inward and Product Identity Viamed** Revision Document ID166168 Date Revision 25 Oct 2024 Reviewed 25 Oct 2024 Audit 23 Analysis of Data Viamed

Planning of product realization	Revision Document ID158752 Date Revision 06 Aug 2024 Reviewed 06 Aug 2024 Audit 10 Documentation Control Viamed Revision Document ID159363 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 10 Documentation Control VST Revision Document ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Reviewed 13 Aug 2024 Revision 13 Aug 2024 Reviewed 13 Aug	
7.2 Customer-related		
processes		
7.2.1	Top Level Document:	Process: 7732
The organization shall	Audit 02 Contract	Audit 22 Post Market Survellance
determine:	Review and Sales	Viamed 24 Aug 2016
a) requirements	Order Processing	Process: 7715
specified by the	Viamed	Audit 02 Contract Review Viamed 24
customer, including the	Revision Document	Aug 2016
requirements for	ID163469	Process: 7825
delivery and	Date Revision 27 Sep	Responsibility Allocation : Order
postdelivery activities;	2024 Reviewed 27 Sep	Picking 06 Sep 2017
b) requirements not	2024	Process: 5
stated by the customer	Top Level Document:	Responsibility Allocation : Processing
but necessary for	VM3COP03.07	Of Sales Orders 16 Feb 2016
specified or intended	Humanmed Order	Process: 7825
use, as known;	Checking	Responsibility Allocation : Order
c) applicable regulatory		Picking 06 Sep 2017
requirements related to		Process: 7825
the product;	Date Revision 27 Sep	Responsibility Allocation : Order
d) any user training	2017 Reviewed 27 Sep	Picking 06 Sep 2017

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Top Level Document:

Process: 7

Responsibility Allocation : Checking Of

2017

needed to ensure

specified performance

and safe use of the medical device;
e) any additional requirements determined by the organization

Determination of

Determination of requirements related to product

VM3COP03.08 Humanmed Order

Processing

Revision Document

ID24775

Date Revision 22 Dec 2017 Reviewed 22 Dec

2017

Top Level Document: VM3COP12.01 Viamed

Policy on End User

Training UK

Revision Document

ID85827

Date Revision 29 Mar

2022 Reviewed 29 Mar

2022

Top Level Document:

VOP 03 Contract

Review, Enquires,

Office Processes

Revision Document

ID77875

Date Revision 15 Dec

2021 Reviewed 21 May

2024

Audit 22 Post Market Survellance Viamed

Revision Document

ID186382

Date Revision 23 May

2025 Reviewed 23 May

2025

VM3COP20.31 Export

Order Processing

Revision Document

ID165205

Date Revision 16 Oct

2024 Reviewed 16 Oct

2024

VM3COP03.01 Order

Processing Priorities

Revision Document

ID20049

Date Revision 15 May

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

2017 Reviewed 15 May 2017

VM3COP20.30 UK

Order Processing

Revision Document

ID165199

Date Revision 16 Oct

2024 Reviewed 16 Oct

2024

Oxygen Sensor

Training Powerpoint

Revision Document

ID15736

Date Revision 24 Sep

2015 Reviewed 25 Oct

2016

Oxygen Sensor

Training Video

Revision Document

ID15737

Date Revision 24 Sep

2015 Reviewed 24 Sep

2015

Resuscitation Unit and

TC400 Training

Information

Resuscitation Cabinet

Training

Revision Document

ID4111

Date Revision 09 Jul

2008 Reviewed 09 Jul

2008

Resuscitation Unit

Maintenance Therapy

Equipment Suction

Controller Unit and

TC400 Training

Information Therapy

Workshop Inst.

Revision Document

ID4122

Date Revision 09 Jul

2008 Reviewed 09 Jul

2008

Single Use Surgical Training Information certificates

Revision Document ID20220

Date Revision 19 May 2017 Reviewed 19 May 2017

SpO2 800 series

Training Information

Revision Document ID12687

Date Revision 02 Jul

2013 Reviewed 02 Jul 2013

TECcare Training Material

Revision Document ID11826

Date Revision 11 Jun 2012 Reviewed 11 Jun 2012

Temperature Probe Training Material

Revision Document ID18169

Date Revision 05 Dec 2016 Reviewed 05 Dec 2016

Tom Thumb Training Information

Revision Document ID7880

Date Revision 07 Mar 2011 Reviewed 07 Mar 2011

Tom Thumb Training Information 2009

Revision Document ID15644

Date Revision 16 Sep 2015 Reviewed 16 Sep 2015

Tom Thumb Training Information Training

Manual Training Information

Revision Document

ID2973

Date Revision 31 Jan

2008 Reviewed 31 Jan

2008

Tom Thumb Training Information Training

V1.1

Revision Document

ID15641

Date Revision 16 Sep

2015 Reviewed 16 Sep

2015

Training information Infant Resusitation

Unit

Revision Document

ID8665

Date Revision 12 Oct

2011 Reviewed 12 Oct

2011

VM-2500 Product

Training Materials -

Frequently Asked

Questions

Revision Document

ID6967

Date Revision 17 Mar

2010 Reviewed 17 Mar

2010

VM-2500 Product

Training Materials

Capnography Product

Application Notes

Revision Document

ID6749

Date Revision 08 Feb

2010 Reviewed 08 Feb

2010

VM-2500 Product

Training Materials

Capnography Product

Presentation MASTER

Revision Document ID6750

Date Revision 08 Feb 2010 Reviewed 08 Feb 2010

VM-2500 Product Training Materials Mainstream or Sidestream Capnography

Revision Document

ID6753

Date Revision 08 Feb 2010 Reviewed 08 Feb 2010

Audit 01 Picking packing Viamed

Revision Document ID173579 Date Revision 22 Jan

2025 Reviewed 22 Jan 2025

Infant Resuscitation Cabinet - Training Assessment Form

Revision Document

Revision Document ID14334

Date Revision 25 Sep 2014 Reviewed 25 Sep 2014

VM3COP20.32 Order Checking

Revision Document ID34889

Date Revision 01 Apr 2020 Reviewed 01 Apr 2020

Audit 16 Sales and Marketing Viamed

Revision Document

ID159461

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

7.2.2 The organization shall review the requirements related to Order Processing product. This review shall be conducted prior to the organization's commitment to supply product to the customer 2024 (e.g. submission of tenders, acceptance of contracts or orders, acceptance of **Office Processes** changes to contracts or orders) and shall ensure that: a) product requirements are defined and documented; b) contract or order requirements differing from those previously expressed are resolved; Date Revision 25 Oct c) applicable regulatory 2024 Reviewed 25 Oct requirements are met; d) any user training identified in accordance with 7.2.1 is Managment Viamed available or planned to be available; e) the organization has the ability to meet the defined requirements. Records of the results of Audit 10 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 Documentation

Top Level Document: Audit 02 Contract Review and Sales Viamed Revision Document ID163469 Date Revision 27 Sep 2024 Reviewed 27 Sep **Top Level Document: VOP 03 Contract** Review, Enquires, Revision Document ID77875 Date Revision 15 Dec 2021 Reviewed 21 May 2024 Audit 11 Repairs, Servicing and Returns Viamed Revision Document ID166158 2024 **Audit 20 Process** verification to Revision Document ID159389 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Documentation **Control Viamed Revision Document** ID159363 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

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 Process: 5871 Check Sale Or Returns 17 Feb 2016 Process: 5872 Check Sale Or Returns Export 17 Feb 2016 Process: 7990 Verification Invoice Details Accounts 07 Feb 2022

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Audit 10

shall be confirmed by the organization before Revision Document 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

Control VST ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

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

Process: 5943

Check Cardea And Multiquote 08 Mar

2016

Process: 7678

Check Catalog 360 Circle For Quotes

And Orders 08 Apr 2016

Process: 7758

Check For GHX Orders 17 Jan 2017

7.2.3

The organization shall plan and document arrangements for communicating with customers in relation to:

a) product information;

b) enquiries, contracts or order handling,

including amendments;

c) customer feedback, including complaints;

d) advisory notices. The organization shall communicate with

regulatory authorities in accordance with applicable

regulatory

requirements.

Communication

VOP 03 Contract Review, Enquires,

Top Level Document:

Office Processes

Revision Document

ID77875

Date Revision 15 Dec

2021 Reviewed 21 May

2024

Top Level Document:

VOP 19 Feedback

Customer Complaints Vigilance and

Notifications Viamed

Ltd

Revision Document

ID132118

Date Revision 18 Oct

2023 Reviewed 18 Oct

2023

Top Level Document: Audit 02 Contract Review and Sales

Order Processing

Viamed

Revision Document

ID163469

Date Revision 27 Sep

62 of 158

2024 Reviewed 27 Sep

2024

VM3COP27.31

Processing Proforma

Invoices and Quotations

Revision Document

ID69812

Date Revision 15 Sep

2021 Reviewed 15 Sep

2021

VM3COP20.05 New

Orders - How to enter into Opera Viamed

Revision Document

ID13695

Date Revision 12 May

2014 Reviewed 12 May

2014

VM3COP20.32 Order

Checking

Revision Document

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

Process: 7760

Send Service Offers 31 Jan 2017

Process: 7670

Humanmed general Issues 09 Mar

2016

Process: 7782

Remove Started But Not Used Order

Numbers 08 Feb 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: 7957

Warehouse Requests 29 May 2020

Process: 6959

Responsibility Allocation : Sales

Forward Orders Review 09 Mar 2016

Process: 6921

Responsibility Allocation : Customer

pricing agreements 09 Mar 2016

Process: 5876

E.Commerce Cardea And Multiquote

17 Feb 2016

Process: 7748

Check Repair Orders 10 Oct 2016

Process: 7860

Goods Out Picking 03 Oct 2017

Process: 5

Responsibility Allocation: Processing

Of Sales Orders 16 Feb 2016

Process: 6

Responsibility Allocation : Updating

Contact Management System 16 Feb

2016

Process: 7

Responsibility Allocation : Checking Of

Sales Orders 16 Feb 2016

Process: 8

Responsibility Allocation : Order And

Status Liaison With Customers 16 Feb

2016

Process: 9

Distribution Of Faxes 16 Feb 2016

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

ID74788

Date Revision 12 Nov 2021 Reviewed 12 Nov

2021

Audit 14 Complaints

and Corrective **Actions Viamed**

Revision Document

ID159455

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 01 Picking packing Viamed

Revision Document

ID173579

Date Revision 22 Jan 2025 Reviewed 22 Jan

2025

Finance Viamed

Revision Document

ID159427

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Audit 16 Sales and **Marketing Viamed**

Revision Document

ID159461

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 22 Post Market Survellance Viamed

Process: 10

Distribution Of Emails 16 Feb 2016

Process: 11

Distribution Of Post 16 Feb 2016

Process: 12

Responsibility Allocation: Sales And

Technical Information Processing 16

Feb 2016 Process: 36

Emailing Of Invoices 16 Feb 2016

Process: 5850

Purchase Order Log 17 Feb 2016

Process: 5875

Check Paypal For Orders 17 Feb 2016

Process: 5857

Customer Service Logs 17 Feb 2016

Process: 5891

Processing Of Repair Quotes And

Orders 25 Feb 2016

Process: 5892

Checking EBay And Amazon For Orders And Messages 25 Feb 2016

Process: 5893

Answering Website Questions 25 Feb

2016

Process: 5899

Proforma And Quote Chasing 25 Feb

2016

Process: 5901

Audit 04 Accounts and Link Call Log Contacts To The CRM 02

Mar 2016

Process: 5913

Check For Humanmed Orders In Logistics Mailbox 03 Mar 2016

Process: 6958

Responsibility Allocation : Shipped

Order Queries 09 Mar 2016

Process: 7686

Thorough Checking Of Awaiting

Action Tray - Priority 8s 21 Apr 2016

Process: 7734

Responsibility Allocation : Humanmed

Order Processing 25 Aug 2016

Process: 7735

Ensure SOR's Are Followed Up 01 Sep

	Revision Document ID186382 Date Revision 23 May 2025 Reviewed 23 May 2025	2016 Process: 7792 Shipped Order Success Report 13 Mar 2017 Process: 7990 Verification Invoice Details Accounts 07 Feb 2022 Process: 7993 Verification Warranty Repairs Customer Approval 07 Feb 2022 Process: 7914 Proofs of Delivery 02 Oct 2018
7.3 Design and development		Process: 7172 Responsibility Allocation : CE Technical Files 09 Mar 2016
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 Viamed Revision Document ID173558 Date Revision 22 Jan 2025 Reviewed 26 Jun 2025 Audit 20 Process verification to Managment Viamed Revision Document ID159389 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 BSI Technical File Design File Requirements Dosier Revision Document ID4959	Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016 Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016 Process: 7172 Responsibility Allocation : CE Technical Files 09 Mar 2016

Date Revision 29 Dec 2008 Reviewed 29 Dec 2008

CE & Design files reorganisation

Revision Document

ID9085

Date Revision 18 Oct

2011 Reviewed 18 Oct

2011

Chart 04 Design and Development

Revision Document

ID8678

Date Revision 12 Oct

2011 Reviewed 12 Oct

2011

Chart 17 Design

Repairs

Revision Document

ID8690

Date Revision 12 Oct

2011 Reviewed 12 Oct

2011

Chart 30 System

Design Plan

Revision Document

ID8703

Date Revision 12 Oct

2011 Reviewed 12 Oct

2011

New Project Design

File Content

Revision Document

ID9093

Date Revision 18 Oct

2011 Reviewed 18 Oct

2011

VM3COP16 Design and

Design Changes

Design requirements

Revision Document

ID7396

Date Revision 10 Jan

2011 Reviewed 10 Jan

2011 **Audit 12 CE Files** Viamed Revision Document ID181242 Date Revision 31 Mar 2025 Reviewed 31 Mar 2025

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:

b) the review(s) needed || **Responsibility** , **Staff** 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

a) the design and

development stages;

Top Level Document: VM3COP27.11 Performing a **Technical File PMS** and risk assessment Revision Document ID75465 Date Revision 18 Nov 2021 Reviewed 18 Nov 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 and Staffing Issues, Training, Roles and **Tasks** Revision Document

ID151817

Date Revision 21 May 2024 Reviewed 21 May 2024

VM3COP16 Design and **Design Changes** Design requirements **Revision Document**

ID7396

Date Revision 10 Jan

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

Process: 7172

Responsibility Allocation : CE Technical Files 09 Mar 2016

design and development outputs to 2011 design and development inputs; f) the resources needed Revision Document including necessary competence of personnel **Design and** development planning 2013

2011 Reviewed 10 Jan

VM3COP27.07 Project

Manager

ID12734

Date Revision 11 Jul

2013 Reviewed 11 Jul

VM3COP27.12 Clinical **Evaluation Risk** assessment Technical

Files

Revision Document

ID15453

Date Revision 11 Aug

2015 Reviewed 11 Aug

2015

Audit 03 Design **Control Viamed**

Revision Document

ID173558

Date Revision 22 Jan

2025 Reviewed 26 Jun

2025

Audit 20 Process

verification to

Managment Viamed

Revision Document

ID159389

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 08 Training, Competence and

Human Resources

Viamed

Revision Document

ID162725

Date Revision 19 Sep

2024 Reviewed 19 Sep

2024

Audit 12 CE Files

Viamed

Revision Document

ID181242

Date Revision 31 Mar 2025 Reviewed 31 Mar 2025

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

(see 4.2.5). These

inputs shall include:

a) functional,

performance, usability

and safety

requirements, according to the

intended use;

b) applicable regulatory Date Revision 22 Jan

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

and records maintained Revision Document

ID25632

Date Revision 19 Mar

2018 Reviewed 19 Mar

2018

Audit 03 Design

Control Viamed

Revision Document

ID173558

2025 Reviewed 26 Jun

2025

Audit 20 Process

verification to

Managment Viamed

Revision Document

ID159389

Date Revision 13 Aug

2024 Reviewed 13 Aug

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

Process: 7172

Responsibility Allocation : CE

Technical Files 09 Mar 2016

essential for design and |2024| 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.

Audit 23 Analysis of Data Viamed

Revision Document ID158752

Date Revision 06 Aug 2024 Reviewed 06 Aug

2024 **Audit 12 CE Files**

Viamed

Revision Document

ID181242

Date Revision 31 Mar 2025 Reviewed 31 Mar 2025

Design and development inputs

7.3.4

Design and development outputs

shall:

a) meet the input

requirements for design and

development;

b) provide appropriate

information for

purchasing, production

and service provision; c) contain or reference

product acceptance

criteria;

d) specify the

characteristics of the

product that are

essential for its safe

and proper use.

The outputs of design and development shall

be in a form suitable

for verification against

the design

and development

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 Viamed

Revision Document

ID173558

Date Revision 22 Jan

2025 Reviewed 26 Jun

2025

Audit 23 Analysis of

Data Viamed

Revision Document

ID158752

Date Revision 06 Aug

2024 Reviewed 06 Aug

2024

Audit 12 CE Files

Viamed

Revision Document

Process: 7716

Audit 03 Design Control Viamed 24

Aug 2016

Process: 7172

Responsibility Allocation : CE Technical Files 09 Mar 2016

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	ID181242 Date Revision 31 Mar 2025 Reviewed 31 Mar 2025	
7.3.5	Audit 12 CE Files	Process: 7172
Design and	Viamed	Responsibility Allocation : CE
development review	Revision Document	Technical Files 09 Mar 2016
	ID181242	
	Date Revision 31 Mar	
	2025 Reviewed 31 Mar	
	2025]
7.3.5	Top Level Document:	Process: 7716
At suitable stages,	VOP 17 Design	Audit 03 Design Control Viamed 24
systematic reviews of	Research and	Aug 2016
design and	Development	Process: 7172
development shall be	Revision Document	Responsibility Allocation : CE
performed in	ID25632	Technical Files 09 Mar 2016
accordance	Date Revision 19 Mar	
with planned and	2018 Reviewed 19 Mar	
documented	2018	
arrangements to:	Audit 03 Design	
a) evaluate the ability	Control Viamed	
of the results of design	Revision Document	
and development to	ID173558	
meet requirements; b) identify and propose	Date Revision 22 Jan 2025 Reviewed 26 Jun	
necessary actions.	2025 Reviewed 20 Juli 2025	
Participants in such	Audit 12 CE Files	
reviews shall include	Viamed	
representatives of	Revision Document	
functions concerned	ID181242	
with the design and	Date Revision 31 Mar	
development stage	2025 Reviewed 31 Mar	
being reviewed, as well	2025	
as other specialist		
-		
personnel.		
Records of the results of		
-		

be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5).

7.3.6 **Top Level Document:** Design and **VOP 17 Design** development Research and verification shall be Development performed in **Revision Document**

> ID25632 Date Revision 19 Mar

2018 Reviewed 19 Mar

Top Level Document: VOP 15 Data and **Information Analysis Revision Document**

ID137913 Date Revision 27 Dec 2023 Reviewed 27 Dec

2023

Audit 12 CE Files Viamed

Revision Document ID181242

Date Revision 31 Mar 2025 Reviewed 31 Mar 2025

Audit 03 Design **Control Viamed**

Revision Document Date Revision 22 Jan 2025 Reviewed 26 Jun 2025

Process: 7172

Responsibility Allocation : CE Technical Files 09 Mar 2016

accordance with planned and documented arrangements to ensure 2018 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 ID173558 medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. Records of the results and conclusions of the

verification and necessary actions shall be maintained (see 4.2.4 and 4.2.5). Design and development verification 7.3.7

Design and

validation

development

Audit 12 CE Files

Viamed

Revision Document

ID181242

Date Revision 31 Mar 2025 Reviewed 31 Mar

2025

QC 30b Project **Verification &**

Validation Summary

Master

Revision Document

ID25482

Date Revision 01 Mar 2018 Reviewed 01 Mar

2018

Process: 7172

Responsibility Allocation : CE

Technical Files 09 Mar 2016

7.3.7

Design and development validation Research and shall be performed in

accordance with planned and

documented

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

Top Level Document:

VOP 17 Design

Development

Revision Document

ID25632

Date Revision 19 Mar

arrangements to ensure 2018 Reviewed 19 Mar

2018

Top Level Document: VOP 15 Data and Information Analysis

Revision Document

ID137913

Date Revision 27 Dec

2023 Reviewed 27 Dec

2023

Audit 03 Design **Control Viamed**

Revision Document ID173558

Process: 7716

Audit 03 Design Control Viamed 24

Aug 2016

Process: 7723

Audit 10b Process Verification Viamed

24 Aug 2016

Process: 7172

Responsibility Allocation : CE

Technical Files 09 Mar 2016

rationale for sample size. Design validation shall be conducted on representative product. Viamed Representative product Revision Document includes initial production units, Date Revision 31 Mar batches or their eguivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5). As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met

Date Revision 22 Jan 2025 Reviewed 26 Jun 2025

Audit 12 CE Files ID181242

2025 Reviewed 31 Mar 2025

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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).

The organization shall

document procedures

for transfer of design

manufacturing. These

development outputs

manufacturing before

specifications and that

product requirements.

of the transfer shall be

recorded (see 4.2.5).

capability can meet

and development

that design and

are verified

as suitable for

becoming final

production

production

outputs to

7.3.8

Top Level Document:

VOP 17 Design Research and

Revision Document

Development

ID25632

Date Revision 19 Mar procedures shall ensure 2018 Reviewed 19 Mar

2018

Audit 03 Design **Control Viamed**

Revision Document

ID173558

Date Revision 22 Jan 2025 Reviewed 26 Jun

2025

Audit 12 CE Files

Viamed

Revision Document

Results and conclusions ID181242

Date Revision 31 Mar 2025 Reviewed 31 Mar

2025

Process: 7716

Audit 03 Design Control Viamed 24

Aug 2016

Process: 7722

Audit 10 Documentation Control

Viamed 24 Aug 2016

Process: 7172

Responsibility Allocation : CE

Technical Files 09 Mar 2016

Design and

7.3.9

The

development transfer

The organization shall document procedures

to control design and

development changes.

organization shall

Top Level Document:

VOP 17 Design Research and

Development

Revision Document

ID25632

Date Revision 19 Mar

Process: 7716

Audit 03 Design Control Viamed 24

Aug 2016

Process: 7726

Audit 14 Complaints And Corrective

Actions Viamed 24 Aug 2016

Process: 7172

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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, Date Revision 31 Mar the changes shall be: a) reviewed; b) verified; c) validated, as appropriate; d) approved. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes. Records of changes, their review and any necessary actions shall be maintained (see 4.2.5). **Control of** design and

2018 Reviewed 19 Mar 2018 Audit 03 Design

Control Viamed Revision Document ID173558

Date Revision 22 Jan 2025 Reviewed 26 Jun

2025

Audit 12 CE Files Viamed

Revision Document ID181242

2025 Reviewed 31 Mar 2025

QC 28B Design Changes

Revision Document

ID25508

Date Revision 05 Mar 2018 Reviewed 05 Mar 2018

Responsibility Allocation : CE Technical Files 09 Mar 2016

7.3.10

The organization shall maintain a design and development file for each medical device

development changes

Audit 03 Design **Control Viamed**

Revision Document ID173558

Date Revision 22 Jan

Process: 7722

Audit 10 Documentation Control

Viamed 24 Aug 2016

Process: 7716

Audit 03 Design Control Viamed 24

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

2025 Reviewed 26 Jun 2025 Audit 12 CE Files Viamed Revision Document ID181242 Date Revision 31 Mar 2025 Reviewed 31 Mar 2025

Aug 2016 **Process: 7172**Responsibility Allocation : CE

Technical Files 09 Mar 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 ID73132

Date Revision 25 Oct 2021 Reviewed 25 Oct 2021

VM3COP27.34 Sending Purchase Orders to Suppliers

Revision Document ID17070

Date Revision 22 Jun 2016 Reviewed 22 Jun 2016

VM3COP04.01 QC06 Supplier Questionnaire ISO Questionnaire Viamed Blank

Revision Document

Process: 5850

VM3COP04 Purchasing Purchase Order Log 17 Feb 2016

Process: 7707

Send Purchase Orders To Suppliers 13

Jun 2016

The organization shall

ID21304 Date Revision 06 Aug 2017 Reviewed 06 Aug 2017

7.4.1

document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the 2025 Reviewed 30 Oct 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

c) based on the effect of the purchased product on the quality of the medical device;

performance of the

supplier;

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

Top Level Document:

VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier **Returns and Rejection**

Revision Document ID200924

**Date Revision 30 Oct 2025

Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection **Revision Document**

ID181426 Date Revision 02 Apr

2025 Reviewed 02 Apr 2025

Top Level Document: VOP 21 Risk, Risk

Management and Risk

Analysis

Revision Document ID177830

Date Revision 03 Mar 2025 Reviewed 03 Mar

2025

Audit 05 Purchasing suppliers Viamed

Revision Document ID159433

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

Audit 09 Goods Inward and Product Identity Viamed

Process: 7717

Audit 05 Purchasing Suppliers Viamed

24 Aug 2016 Process: 7725

Audit 12 CE Files Viamed 24 Aug 2016

Process: 5855

Purchase Order Requirements

Teledyne 17 Feb 2016

Process: 8030

Purchase Order Invoice Review 23 Jun

2023

into the supplier reevaluation 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 reevaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).

Revision Document ID166168 Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

Purchasing process

7.4.2 Purchasing information VOP 05 Supplier 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 Repairs, Inspection / personnel; d) quality management system requirements. The organization shall

ensure the adequacy of

Top Level Document: Control, Supplier Review, Purchase Orders, Supplier **Returns and Rejection Revision Document** ID200924 **Date Revision 30 Oct 2025 Reviewed 30 Oct

2025 **Top Level Document:** VOP 20 Goods in Purchases, Returns, Rejection Revision Document ID181426 Date Revision 02 Apr 2025 Reviewed 02 Apr

Process: 7717

Audit 05 Purchasing Suppliers Viamed 24 Aug 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: 28

Supplier Review 16 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

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specified purchasing requirements prior to their communication to the supplier. Purchasing information Date Revision 13 Aug shall include, as applicable, a written agreement that the supplier notify the organization of changes Identity Viamed in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. Revision Document 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

2025

Audit 05 Purchasing suppliers Viamed

Revision Document ID159433

2024 Reviewed 13 Aug 2024

Audit 09 Goods Inward and Product

Revision Document ID166168

Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

Audit 23 Analysis of Data Viamed

ID158752

Date Revision 06 Aug 2024 Reviewed 06 Aug 2024

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: 7683

Check Stock For Proforma 18 Apr 2016

Process: 7784

Check Returns Supplier Envited 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: 7826

Goods In Processes 06 Sep 2017

Process: 7923

Review Of Credits Received From

Suppliers 08 Jan 2019

Process: 6819

Supplier Payments and Invoice

processing 09 Mar 2016

Process: 7882

Purchase Payments 23 Oct 2017

Process: 7933

Purchasing Invoice Processing 22 Mar

Process: 8030

Purchase Order Invoice Review 23 Jun

2023

7.4.3 The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the Date Revision 02 Apr 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).

Top Level Document: VOP 06 Measurement Control Viamed VST, Calibration, QA Stock **Revision Document** ID168580 Date Revision 22 Nov 2024 Reviewed 22 Nov 2024 **Top Level Document:** VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement Revision Document ID137933

Date Revision 27 Dec 2023 Reviewed 27 Dec 2023 **Top Level Document:** VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection **Revision Document** ID181426 2025 Reviewed 02 Apr 2025 **Audit 09 Goods** Inward and Product **Identity Viamed** Revision Document ID166168 Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

Process: 7717

Audit 05 Purchasing Suppliers Viamed 24 Aug 2016

Process: 7721

Audit 09 Goods Inward And Product Identity Viamed 24 Aug 2016

Process: 8030

Purchase Order Invoice Review 23 Jun

2023

Verification of purchased product		
7.5 Production and service provision		
7.5.1	Top Level Document:	Process: 7714
Production and service	VOP 06 Measurement	Audit 01 Picking Packing Viamed 24
provision shall be	Control Viamed VST,	Aug 2016
planned, carried out,	Calibration, QA Stock	Process: 7719
monitored and	Revision Document	Audit 07 Handling And Storage
controlled to ensure	ID168580	Viamed 24 Aug 2016
that	Date Revision 22 Nov	Process: 7725
product conforms to	2024 Reviewed 22 Nov	Audit 12 CE Files Viamed 24 Aug 2016
specification. As	2024	Process: 7727
appropriate,	Top Level Document:	Audit 15 Production Viamed 24 Aug
production controls	VOP 08 Production,	2016
shall include but are	Reworks, New	Process: 7673
not limited to:	Production	Check Expiry Dated Stock 09 Mar 2016
a) documentation of	Revision Document	Process: 6850
procedures and	ID31072	Current Stock Levels 09 Mar 2016
methods for the control	Date Revision 30 Sep	Process: 6838
of production (see	2019 Reviewed 30 Sep	Opera Negative Stock 09 Mar 2016
4.2.4);	2019	Process: 5858
b) qualification of	Top Level Document:	Opera Stock Adjustments 17 Feb 2016
infrastructure;	VOP 07 Stock Control,	Process: 5935
c) implementation of	Handling, Control of	Stock Allocations 05 Mar 2016
monitoring and	Labelling, Storage,	Process: 6945
measurement of	Movement	Missing Stock or Adjustments 09 Mar
process parameters and	Revision Document	2016
product characteristics;	II .	Process: 6955
d) availability and use	Date Revision 27 Dec	Production Requirements 09 Mar 2016
of monitoring and	2023 Reviewed 27 Dec	Process: 7689
measuring equipment;	2023	Move Stock From QA Shelf To Stock
e) implementation of	Top Level Document:	Shelf Monday 21 Apr 2016
defined operations for	VOP 22 Picking and	Process: 7694
labelling and	Packing Dispatch and	Move Stock From QA Shelf To Stock
packaging;	Goods Out	Shelf Tuesday 28 Apr 2016
f) implementation of	Revision Document	Process: 7695
product release,	ID164829	Top Up Quick Shipping Shelves 28 Apr
delivery and post-	Date Revision 14 Oct	2016
delivery activities.	2024 Reviewed 14 Oct	Process: 7985
The organization shall	2024	OverDue Servicing 03 Feb 2022
establish and maintain	Top Level Document:	
I .	VOP 20 Goods in	II.

each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record VOP 09 Repairs and shall be verified and approved. **Control of** production and service provision

Purchases, Returns, Repairs, Inspection / Rejection

Revision Document ID181426

Date Revision 02 Apr

2025 Reviewed 02 Apr 2025

Top Level Document:

Servicing

Revision Document

ID137919

Date Revision 27 Dec 2023 Reviewed 27 Dec 2023

VM3COP20.37

Generating a New

Service Visit

Revision Document

ID17116

Date Revision 28 Jun 2016 Reviewed 28 Jun

2016

Audit 01 Picking packing Viamed

Revision Document

ID173579

Date Revision 22 Jan

2025 Reviewed 22 Jan

2025

Audit 07 Handling and Storage Viamed

Revision Document

ID184932

Date Revision 09 May

2025 Reviewed 09 May

2025

Audit 15 Production

Viamed

Revision Document

ID191692

Date Revision 21 Jul

2025 Reviewed 21 Jul

2025

Audit 06 Calibration VIAMED

Revision Document ID186878

Date Revision 30 May 2025 Reviewed 30 May 2025

Audit 09 Goods Inward and Product **Identity Viamed**

Revision Document ID166168

Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

Audit 24 Service Logs Viamed

Revision Document ID159493 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

7.5.2

its use;

The organization shall document requirements for cleanliness of product or contamination control of product if: a) product is cleaned by 2021 Reviewed 01 Aug 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

c) product cannot be

sterilization or its use, and its cleanliness is of

cleaned prior to

Top Level Document:

VM3COP02.01

Exclusions to Viamed ISO13485:2016

boundaries of ISO

Revision Document

ID74571

Date Revision 10 Nov

2025

Audit 07 Handling and Storage Viamed

Revision Document ID184932

Date Revision 09 May 2025 Reviewed 09 May

2025

Process: 7717

Audit 05 Purchasing Suppliers Viamed

24 Aug 2016

Process: 7719

Audit 07 Handling And Storage

Viamed 24 Aug 2016

significance in use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; e) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process. **Cleanliness of** product

The organization shall

requirements for

medical device

installation and

acceptance criteria

If the agreed customer

requirements allow

medical device to be

external party other

than the organization

installation of the

performed by an

or its supplier, the

organization shall

requirements for

medical device

installation and

Records of medical

verification of

installation.

provide documented

for verification of

installation, as

appropriate.

7.5.3

document

Resuscitation Unit and Process: 7717

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

Audit 05 Purchasing Suppliers Viamed

24 Aug 2016

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device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5). **Installation activities**

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

Viamed

Revision Document

ID159493

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

7.5.4

If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for

performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its

a) to determine if the

information is to be

supplier:

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

ID137919

Date Revision 27 Dec

2023 Reviewed 27 Dec

2023

VM3COP20.27 Annual

Services for

Resuscitation

Cabinets

Revision Document

ID24509

Date Revision 06 Dec

handled as a complaint; 2017 Reviewed 06 Dec

Process: 5857

Customer Service Logs 17 Feb 2016

Process: 7722

Audit 10 Documentation Control

Viamed 24 Aug 2016

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

2017
VM3COP20.37
Generating a New
Service Visit
Revision Document
ID17116

Date Revision 28 Jun 2016 Reviewed 28 Jun 2016

2016 X**M2COD**EC

VM3COP50.12 Quality Control / Service Checks Tom Thumb

Revision Document ID15367

Date Revision 05 Aug 2015 Reviewed 05 Aug 2015

Audit 11 Repairs, Servicing and Returns Viamed

Revision Document ID166158

Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

Audit 14 Complaints and Corrective Actions Viamed

Revision Document

ID159455 Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Audit 23 Analysis of Data Viamed

Revision Document ID158752

Date Revision 06 Aug 2024 Reviewed 06 Aug 2024

Audit 24 Service Logs Viamed

Revision Document ID159493

Date Revision 13 Aug

	2024 Reviewed 13 Aug 2024	
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 ID74571 Date Revision 10 Nov 2021 Reviewed 01 Aug 2025	Process: 7722 Audit 10 Documentation Control Viamed 24 Aug 2016 Process: 7717 Audit 05 Purchasing Suppliers Viamed 24 Aug 2016
7.5.6	Top Level Document:	Process: 7849
The organization shall	VOP 27 Software	Review Product Failures New Codes 28
validate any processes	Validation	Sep 2017
for production and	Revision Document	Process: 7870
service provision	ID91486	Software Validation Non Conformance
where the resulting	Date Revision 10 Jun	Product Risk Feedback Loop 15 Oct
output cannot be or is	2022 Reviewed 10 Jun	2017
not verified by	2022	Process: 7879
subsequent monitoring	Top Level Document:	Software Validation Scheduled Tasks
or measurement and,	VOP 15 Data and	And Audits 22 Oct 2017
as a consequence,	Information Analysis	Process: 7850
deficiencies become	Revision Document	Software Validation Scan Incorrect
apparent only after the	ID137913	Product 01 Oct 2017
product is in use or the	Date Revision 27 Dec	Process: 7851
service has been	2023 Reviewed 27 Dec	Software Validation Scan Un-QA
delivered.	2023	Product To Order 01 Oct 2017
Validation shall	VM3COP18 Post	Process: 7852
demonstrate the ability	Market Surveilance	Software Validation Expired Stock 01
of these processes to	Revision Document	Oct 2017
achieve planned results	ID75985	Process: 7853
consistently.	Date Revision 24 Nov	Software Validation Non Sell Able
The organization shall	2021 Reviewed 24 Nov	Shelf 01 Oct 2017
document procedures	2021	Process: 7854
for validation of	Audit 03 Design	Software Validation In Production List
processes including:	Control Viamed	01 Oct 2017
a) defined criteria for	Revision Document	Process: 7855

review and approval of ID173558 the processes; b) equipment qualification and qualification of personnel; c) use of specific methods, procedures and acceptance criteria; ID166158 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 Control VST application of computer Revision Document software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, Revision Document 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

Date Revision 22 Jan 2025 Reviewed 26 Jun 2025 Audit 11 Repairs, Servicing and Returns Viamed **Revision Document** Date Revision 25 Oct 2024 Reviewed 25 Oct 2024 Audit 10 Documentation Control Viamed Revision Document ID159363 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 10 Documentation ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 24 Service Logs Viamed ID159493 Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

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: 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

product to conform to specifications.
Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5). Validation of processes for production and service provision

Top Level Document: VM3COP02.01

Exclusions to Viamed

boundaries of ISO

ISO13485:2016

Revision Document ID74571

Date Revision 10 Nov 2021 Reviewed 01 Aug 2025

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

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

following product or

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		
7.5.8	Top Level Document:	Process: 8024
The organization shall	VOP 07 Stock Control,	Discontinue/Supersede Stock 01 Mai
document procedures	Handling, Control of	2023
for product	Labelling, Storage,	Process: 8095
identification and	Movement	Medica Pallet - Return Contents To
identify product by	Revision Document	Stock/exhibition 21 May 2025
suitable	ID137933	Stock/cambition 21 way 2025
means throughout	Date Revision 27 Dec	
product realization.	2023 Reviewed 27 Dec	
The organization shall	2023 Reviewed 27 Dec 2023	
identify product status	Top Level Document:	
with respect to	VOP 20 Goods in	
monitoring and		
· ·	Purchases, Returns,	
measurement	Repairs, Inspection /	
requirements	Rejection	
throughout product	Revision Document	
realization.	ID181426	
Identification of	Date Revision 02 Apr	
product status shall be	2025 Reviewed 02 Apr	
maintained	2025	
	Audit 07 Handling and	
storage, installation and		
0 1	Revision Document	
ensure that only	ID184932	
product that	Date Revision 09 May	
has passed the required	_	
inspections and tests or		
released under an	Audit 09 Goods	
authorized concession	Inward and Product	
is dispatched,	Identity Viamed	
used or installed.	Revision Document	
If required by	ID166168	
applicable regulatory	Date Revision 25 Oct	
requirements, the	2024 Reviewed 25 Oct	
organization shall	2024	
document a system to	Audit 11 Repairs,	
assign	Servicing and Returns	
unique device	Viamed	
identification to the	Revision Document	
medical device.	ID166158	
The organization shall	Date Revision 25 Oct	
document procedures	2024 Reviewed 25 Oct	
T = 2 = 2 = 2 = 2 = 2 = 2 = 2 = 2 = 2 =		

to ensure that medical devices returned to the organization are identified and distinguished from conforming product. Identification 7.5.9	VM3COP14.01	
Traceability	Disposition of Documents / Records. Revision Document ID15464 Date Revision 14 Aug 2015 Reviewed 14 Aug 2015	
7.5.9.1	VM3COP14.01	
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	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	
maintained (see 4.2.5). General	Revision Document ID75624 Date Revision 22 Nov 2021 Reviewed 22 Nov 2021 Audit 07 Handling and Storage Viamed Revision Document	
	ID184932 Date Revision 09 May 2025 Reviewed 09 May 2025 Audit 10 Documentation Control Viamed Revision Document ID159363 Date Revision 13 Aug	

2024 Reviewed 13 Aug 2024 Audit 10 Documentation Control VST Revision Document ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

7.5.9.2

The records required for traceability shall include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements. The organization shall require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.5). Particular requirements for

implantable medical

devices

Audit 09 Goods Inward and Product Identity Viamed Revision Document

Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

ID166168

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

ID137919

Date Revision 27 Dec 2023 Reviewed 27 Dec

2023

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 Viamed

Revision Document

ID184932

Date Revision 09 May 2025 Reviewed 09 May 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

Process: 7863

Maintain Repair Codes List 05 Oct

2017

Process: 6847

Responsibility Allocation : Quarantine

Repairs 09 Mar 2016

Process: 6862

Current Repairs 09 Mar 2016

Process: 7674

Check Repairs Ready For Invoice List

10 Mar 2016 **Process: 7897**

Daily O2 Sensors Returns 04 Jan 2018

Process: 7944

Sealant, Glues, Greases, Sprays, Gases

And Tapes You Use In Production,

Service And Repairs For Viamed And

VST 09 Oct 2019 **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: 8060

Sealant, Glues, Greases, Sprays, Gases

And Tapes You Use In Production,

Service And Repairs For Viamed And

VST Phils Issue 03 Jan 2024

2025

Audit 09 Goods **Inward and Product Identity Viamed**

Revision Document ID166168

Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

Audit 11 Repairs, Servicing and Returns Viamed

Revision Document ID166158 Date Revision 25 Oct

2024 Reviewed 25 Oct 2024

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 | Handling, Control of parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed expected conditions and hazards during processing, storage, handling, and distribution by:

a) designing and

constructing suitable

Top Level Document: VOP 09 Repairs and Servicing

Revision Document

ID137919 Date Revision 27 Dec 2023 Reviewed 27 Dec 2023

Top Level Document: VOP 07 Stock Control, Labelling, Storage,

Revision Document ID137933

Movement

Date Revision 27 Dec 2023 Reviewed 27 Dec 2023

Top Level Document: VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection Revision Document

ID181426 Date Revision 02 Apr

packaging and shipping 2025 Reviewed 02 Apr

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: 7673

Check Expiry Dated Stock 09 Mar 2016

containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are 2014 required, they shall be controlled and recorded (see 4.2.5). Preservation of product

2025

VM3COP20.03 Repair Procedures Goods in

Revision Document ID13703

Date Revision 13 May 2014 Reviewed 13 May

VM3COP20.031

Viamed Repair Procedures Invoicing / customer paperwork

Revision Document ID24753

Date Revision 21 Dec 2017 Reviewed 21 Dec 2017

Audit 01 Picking packing Viamed

Revision Document ID173579

Date Revision 22 Jan 2025 Reviewed 22 Jan 2025

Audit 07 Handling and Storage Viamed

Revision Document ID184932 Date Revision 09 May 2025 Reviewed 09 May

2025

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

ID168580 Date Revision 22 Nov 2024 Reviewed 22 Nov

2024

DO NOT USE

VM3COP11 Calibration Revision Document

ID8713

Process: 7048

Control of monitoring and measuring devices 09 Mar 2016

The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner ID21322 that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring Revision Document 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 readjusted as necessary: such adjustments or readjustments 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

Date Revision 12 Oct 2011 Reviewed 12 Oct 2011 **Explanation Control** of documents

Revision Document

Date Revision 06 Aug 2017 Reviewed 06 Aug 2017

Audit 06 Calibration VIAMED

ID186878 Date Revision 30 May

2025 Reviewed 30 May 2025

Audit 23 Analysis of Data Viamed

Revision Document ID158752

Date Revision 06 Aug 2024 Reviewed 06 Aug 2024

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. 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

Measurement, analysis and improvement

8.1

system.

The organization shall plan and implement the **Performing a** monitoring, measurement, analysis and improvement processes needed to: a) demonstrate conformity of product; b) ensure conformity of 2021 the quality management system; c) maintain the effectiveness of the quality management

Top Level Document: VM3COP27.11

Technical File PMS

and risk assessment

Revision Document

ID75465

Date Revision 18 Nov

2021 Reviewed 18 Nov

Top Level Document: **VOP 13 Process** Monitoring, System

Reviews, Audits,

Management Reviews

Analysis Data PMS

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

This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

General

Post Market

Revision Document

ID135771

Date Revision 28 Nov

2023 Reviewed 26 Jun

2025

Top Level Document: **VOP 15 Data and**

Information Analysis

Revision Document

ID137913

Date Revision 27 Dec

2023 Reviewed 27 Dec

2023

Roles and Titles

Revision Document

ID22144

Date Revision 20 Sep

2017 Reviewed 20 Sep

2017

Audit 22 Post Market

Survellance Viamed

Revision Document

ID186382

Date Revision 23 May

2025 Reviewed 23 May

2025

Audit 23 Analysis of

Data Viamed

Revision Document

ID158752

Date Revision 06 Aug

2024 Reviewed 06 Aug

2024

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

Explanation Employee 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 Saftey Viamed 24

Aug 2016

Process: 7730

Audit 20 Process Verification To

Managment Viamed 24 Aug 2016

Process: 7731

Audit 21 Audit Of Audit Viamed 24

Aug 2016

Process: 7732

Audit 22 Post Market Survellance

Viamed 24 Aug 2016

Process: 7733

Audit 23 Analysis Of Data Viamed 24

Aug 2016

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: 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

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	Top Level Document:	Process: 7877
As one of the	VM3COP27.11	Disaster Planning 21 Oct 2017
measurements of the	Performing a	Process: 5877
effectiveness of the	Technical File PMS	Review Company Data 17 Feb 2016
quality management	and risk assessment	
system, the	Revision Document	
organization	ID75465	
shall gather and	Date Revision 18 Nov	
monitor information	2021 Reviewed 18 Nov	
relating to whether the	2021	
organization has met	Top Level Document:	
customer	VOP 13 Process	
requirements. The	Monitoring, System	
methods for obtaining	Reviews, Audits,	
and using this	Management Reviews	
information shall be	Analysis Data PMS	
documented.	Post Market	
The organization shall	Revision Document	
document procedures	ID135771	
for the feedback	Date Revision 28 Nov	
process. This feedback	2023 Reviewed 26 Jun	
process shall	2025	
include provisions to	Management Review	
gather data from	Revision Document	
production as well as	ID30851	
post-production	Date Revision 18 Sep	
activities.	2019 Reviewed 18 Sep	
The information	2019	
gathered in the	Management reviews	
feedback process shall	Revision Document	
serve as potential input	ID19801	
into risk management	Date Revision 05 May	
for monitoring and	2017 Reviewed 05 May	
maintaining the	2017	
product requirements	Audit 23 Analysis of	

as well as the product realization or improvement processes. If applicable regulatory requirements require the organization to gain Audit 22 Post Market specific experience from postproduction activities, the review of this experience shall form part of the feedback process. Feedback

Data Viamed

Revision Document ID158752

Date Revision 06 Aug 2024 Reviewed 06 Aug

2024

Survellance Viamed

Revision Document ID186382

Date Revision 23 May

2025 Reviewed 23 May 2025

Audit 14 Complaints and Corrective **Actions Viamed**

Revision Document ID159455

Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

8.2.2

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.

These procedures shall include at a minimum requirements and responsibilities for: a) receiving and

recording information;

b) evaluating information to determine if the feedback constitutes a complaint;

c) investigating complaints;

d) determining the need to report the

Top Level Document:

VOP 19 Feedback **Customer Complaints**

Vigilance and

Notifications Viamed

Ltd

Revision Document ID132118

Date Revision 18 Oct 2023 Reviewed 18 Oct

2023

Audit 14 Complaints and Corrective

Actions Viamed

Revision Document

ID159455

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Process: 7743

Customer Complaints Paper File 26

Sep 2016

Process: 7743

Customer Complaints Paper File 26

Sep 2016

information to the appropriate regulatory authorities; e) handling of complaint-related product; f) determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation 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

Top Level Document:
VOP 19 Feedback
Customer Complaints
Vigilance and
Notifications Viamed
Ltd
Revision Document
ID132118

Date Revision 18 Oct

2023

2023 Reviewed 18 Oct

Customer Complaints Paper File 26
Sep 2016 **Process: 7743**

Process: 7743

Customer Complaints Paper File 26 Sep 2016

notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures

If applicable regulatory

requirements require

8.2.3

10/11/2025, 09:48

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

Audit 14 Complaints and Corrective **Actions Viamed** Revision Document ID159455 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 **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

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,

Top Level Document: Audit 02 Contract

Review and Sales

Order Processing

Viamed

Revision Document

ID163469

Date Revision 27 Sep 2024 Reviewed 27 Sep

2024

Top Level Document: VOP 13 Process

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

quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status Date Revision 30 May 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 2024 Reviewed 19 Sep of auditors and conduct 2024 of audits shall ensure objectivity and impartiality of the audit Identity Viamed process. Auditors shall not audit their own work. Records of the audits and their results, including identification Audit 10 of the processes and areas audited and **Control Viamed** the conclusions, shall **Revision Document**

Monitoring, System Reviews, Audits, **Management Reviews Analysis Data PMS** Post Market Revision Document ID135771 Date Revision 28 Nov 2023 Reviewed 26 Jun 2025 **Audit 01 Picking** packing Viamed Revision Document ID173579 Date Revision 22 Jan 2025 Reviewed 22 Jan 2025 Audit 06 Calibration **VIAMED** Revision Document ID186878 2025 Reviewed 30 May 2025 Audit 08 Training, Competence and **Human Resources** Viamed Revision Document ID162725 Date Revision 19 Sep Audit 09 Goods Inward and Product Revision Document ID166168 Date Revision 25 Oct 2024 Reviewed 25 Oct 2024 Documentation

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: 7725 Audit 12 CE Files Viamed 24 Aug 2016 Process: 7724 Audit 11 Repairs And Service Viamed 24 Aug 2016 Process: 7726 Audit 14 Complaints And Corrective Actions Viamed 24 Aug 2016 Process: 7727 Audit 15 Production Viamed 24 Aug 2016 Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016 Process: 7729 Audit 19 Health And Saftey Viamed 24 Aug 2016 Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug 2016 Process: 7731 Audit 21 Audit Of Audit Viamed 24 Aug 2016 Process: 7732 Audit 22 Post Market Survellance Viamed 24 Aug 2016

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Process: 7733

Audit 23 Analysis Of Data Viamed 24

be maintained (see 4.2.5). The management responsible for the area 2024 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

ID159363

Date Revision 13 Aug 2024 Reviewed 13 Aug

Audit 20 Process verification to

Managment Viamed Revision Document

ID159389

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Audit 11 Repairs, Servicing and Returns Viamed

Revision Document

ID166158

Date Revision 25 Oct

2024 Reviewed 25 Oct

2024

Audit 15 Production

Viamed

Revision Document

ID191692

Date Revision 21 Jul

2025 Reviewed 21 Jul

2025

Audit 17 Internal Audits Viamed

Revision Document

ID159465

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 18 Management

Review Viamed

Revision Document

ID159471

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 19 Health and Safety, Working Conditions and **Building Fabric Issues** Aug 2016

Process: 8089

Review Any Outstanding QC 21 Forms

To Sign Off 07 Feb 2025

Viamed

Revision Document

ID159483

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 21 Audit of Audit Viamed

Revision Document

TO 1 TO 10 T

ID159485

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 22 Post Market

Survellance Viamed

Revision Document

ID186382

Date Revision 23 May

2025 Reviewed 23 May

2025

Audit 23 Analysis of

Data Viamed

Revision Document

ID158752

Date Revision 06 Aug

2024 Reviewed 06 Aug

2024

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

10/11/2025, 09:48

2017 Reviewed 24 Oct 2017

Audit 10

Documentation

Control VST

Revision Document

ID159361

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Audit 24 Service Logs

Viamed

Revision Document

ID159493

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

8.2.5

The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These Revision Document methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Monitoring and measurement of processes

Top Level Document:

VOP 13 Process Monitoring, System Reviews, Audits, **Management Reviews Analysis Data PMS**

Post Market

ID135771

Date Revision 28 Nov

2023 Reviewed 26 Jun

2025

Audit 23 Analysis of Data Viamed

Revision Document

ID158752

Date Revision 06 Aug

2024 Reviewed 06 Aug

2024

Audit 10

Documentation Control Viamed

Revision Document

ID159363

Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

Process: 27

Management Reviews And Quality Audits 16 Feb 2016

Audit 10 Documentation Control VST

Revision Document ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

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

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 Viamed

Revision Document ID184932

Date Revision 09 May 2025 Reviewed 09 May 2025

Audit 15 Production Viamed

Revision Document ID191692

Date Revision 21 Jul 2025 Reviewed 21 Jul 2025

include a

determination of the

have been satisfactorily		
completed.		
For implantable		
medical devices, the		
organization shall		
record the identity of		
personnel performing		
any		
inspection or testing.		
Monitoring and		
measurement of		
product		
8.3		Process: 8024
Control of		Discontinue/Supersede Stock 01 Mar
nonconforming		2023
product		Process: 8092
		Sensor Recycle / Depletions Logging 06
		May 2025
8.3.1	Top Level Document:	Process: 7743
The organization shall	VOP 19 Feedback	Customer Complaints Paper File 26
ensure that product	Customer Complaints	Sep 2016
which does not	Vigilance and	Process: 7743
conform to product	Notifications Viamed	Customer Complaints Paper File 26
requirements is	Ltd	Sep 2016
identified and	Revision Document	
controlled to prevent its	ID132118	
unintended use or	Date Revision 18 Oct	
delivery. The	2023 Reviewed 18 Oct	
organization shall	2023	
document	Top Level Document:	
a procedure to define	VOD 10 Non	

a procedure to define VOP 10 Non the controls and related Conformance, responsibilities and Corrective and authorities for the **Preventive Actions** identification, Revision Document documentation, ID124938 segregation, evaluation, Date Revision 24 Jul and disposition of 2023 Reviewed 24 Jul nonconforming 2023 product. VM3COP10.02 Product Recall locate products The evaluation of nonconformity shall out in the Field

111 of 158 10/11/2025, 09:48

Revision Document

ID74788

need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of ID184932 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

Date Revision 12 Nov 2021 Reviewed 12 Nov 2021

Audit 07 Handling and Storage Viamed

Revision Document

Date Revision 09 May 2025 Reviewed 09 May

2025

Audit 09 Goods Inward and Product

Identity Viamed

Revision Document

ID166168

Date Revision 25 Oct 2024 Reviewed 25 Oct 2024

Audit 23 Analysis of Data Viamed

Revision Document ID158752 Date Revision 06 Aug

2024 Reviewed 06 Aug 2024

8.3.2

The organization shall deal with nonconforming product ID184932 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

nonconforming product

ensure that

Audit 07 Handling and Storage Viamed

Revision Document

Date Revision 09 May 2025 Reviewed 09 May

2025

is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession shall be maintained (see 4.2.5). Actions in response to nonconforming product detected before delivery

Top Level Document:

VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed

Ltd

Revision Document ID132118

Date Revision 18 Oct 2023

Audit 14 Complaints and Corrective **Actions Viamed**

Revision Document ID159455 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024

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 2023 Reviewed 18 Oct 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		

The organization shall perform rework in

procedures that takes

account the potential adverse effect of the

rework on the product.

These procedures shall

After the completion of

that it meets applicable

criteria and regulatory

rework, product shall

be verified to ensure

accordance with

documented

undergo the

procedure.

acceptance

same review and

8.3.4

into

Top Level Document: VOP 09 Repairs and Servicing

Revision Document ID137919 Date Revision 27 Dec 2023 Reviewed 27 Dec 2023

Top Level Document: VOP 08 Production, Reworks, New Production Revision Document approval as the original ID31072

Date Revision 30 Sep 2019 Reviewed 30 Sep 2019

Audit 11 Repairs, Servicing and Returns Viamed

Revision Document ID166158 Records of rework shall Date Revision 25 Oct 2024 Reviewed 25 Oct

2024

be maintained (see 4.2.5). **Rework**

requirements.

8.4 The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the ID135771 quality management system. The procedures shall

Top Level Document:

VOP 13 Process Monitoring, System Reviews, Audits, **Management Reviews Analysis Data PMS** Post Market Revision Document Date Revision 28 Nov 2023 Reviewed 26 Jun 2025

Process: 8026

Automotive Competitor Price Review 10 Mar 2023

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
8.5

Top Level Document: VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier **Returns and Rejection Revision Document** ID200924 **Date Revision 30 Oct 2025 Reviewed 30 Oct 2025 **Top Level Document:** VOP 15 Data and **Information Analysis** Revision Document ID137913 Date Revision 27 Dec 2023 Reviewed 27 Dec 2023 Audit 22 Post Market Survellance Viamed Revision Document ID186382 Date Revision 23 May 2025 Reviewed 23 May 2025 Audit 23 Analysis of Data Viamed Revision Document ID158752 Date Revision 06 Aug 2024 Reviewed 06 Aug 2024

Improvement

8.5.1 The organization shall identify and implement Conformance,

Top Level Document: VOP 10 Non

any changes necessary to ensure and maintain **Preventive Actions** 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, 2025 postmarket surveillance, analysis of Review Viamed data, corrective actions, Revision Document preventive actions and management review.

General

Corrective and

Revision Document

ID124938

Date Revision 24 Jul

2023 Reviewed 24 Jul

2023

Audit 06 Calibration

VIAMED

Revision Document

ID186878

Date Revision 30 May

2025 Reviewed 30 May

Audit 18 Management

ID159471

Date Revision 13 Aug

2024 Reviewed 13 Aug

2024

Audit 22 Post Market Survellance Viamed

Revision Document

ID186382

Date Revision 23 May

2025 Reviewed 23 May

2025

Audit 23 Analysis of

Data Viamed

Revision Document

ID158752

Date Revision 06 Aug

2024 Reviewed 06 Aug

2024

Audit 21 Audit of

Audit Viamed

ID159485

Date Revision 13 Aug

Revision Document

2024 Reviewed 13 Aug

2024

8.5.2

The organization shall

Top Level Document: VOP 10 Non

take action to eliminate Conformance, the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;

f) reviewing the

Corrective and **Preventive Actions** Revision Document ID124938 Date Revision 24 Jul 2023 Reviewed 24 Jul 2023 **Audit 20 Process** verification to **Managment Viamed Revision Document** ID159389 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 10 **Documentation Control Viamed** Revision Document ID159363 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 14 Complaints and Corrective **Actions Viamed** Revision Document ID159455 Date Revision 13 Aug 2024 Reviewed 13 Aug 2024 Audit 10 Documentation **Control VST** Revision Document ID159361 Date Revision 13 Aug 2024 Reviewed 13 Aug

2024

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

Top Level Document:
VOP 10 Non
Conformance,
Corrective and
Preventive Actions
Revision Document
ID124938
Date Revision 24 Jul
2023 Reviewed 24 Jul
2023
Audit 14 Complaints
and Corrective
Actions Viamed
Revision Document
ID159455

Date Revision 13 Aug

2024

2024 Reviewed 13 Aug

Process: 7839

Review VIAMED Feedback - Customer Complaints 23 Sep 2017

Process: 7838

Review VIAMED Feedback - Customer Feedback Negative 23 Sep 2017

Process: 7842

Review VIAMED Product Feedback

Negative 23 Sep 2017

Process: 7849

Review Product Failures New Codes 28

Sep 2017

Process: 6866

Internal Process Verification Complete

Systems Review 09 Mar 2016

Process: 7743

Customer Complaints Paper File 26

Sep 2016

Process: 7199

Non Conformities Review Viamed 09

Mar 2016

Process: 7671

Humanmed Non Conformances 09

Mar 2016

Process: 7091

Calibration Index 09 Mar 2016

Process: 7138

Non Conformance Issues Any New

QC21 Forms 09 Mar 2016

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	

Document ID	Sub Processes
ID168096	Viamed ISO 13485:2016 Scope
	Process: 5887 Review ISO/EN Documents 24 Feb 2016
	Process: 7848 Review ISO Scopes 27 Sep 2017
ID74571	VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO
	Process: 5887 Review ISO/EN Documents 24 Feb 2016
	Process: 7871 Review Exclusion From Viamed 13485:2016 And VST
	9001:2015 15 Oct 2017
ID164833	VM3COP00.00 VOP00.00 Viamed Quality Statement policy and objectives
	Process: 23 Company Objectives 16 Feb 2016
	Process: 22 Company Policys 16 Feb 2016
	Process: 7828 Review The Quality Policy Viamed 16 Sep 2017
	Process: 7833 Importance Of Effective Quality Management 20 Sep 2017
ID167103	VM3COP02.02 Viamed Company Responsibilitys organisation chart
	structure
	Process: 5877 Review Company Data 17 Feb 2016
ID176874	Viamed Certification ISO 13485:2016 MD78787
	Process: 5887 Review ISO/EN Documents 24 Feb 2016
ID185333	Viamed Top Level Quality Objectives Viamed Objectives
	Process: 23 Company Objectives 16 Feb 2016
ID120321	VOP 01 Documentation and Records, Control, Creation, Storage,
	Retrieval, Revision Control and Online Records
	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

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: 7987 Sync External Telephone Logs 07 Feb 2022 **Process: 7992** COSHH Datasheet Reminders 07 Feb 2022

Process: 8001 Verification Stock Linked To Documents 08 Feb 2022

Process: 8029 Send Intercompany Invoices To Jean 12 Apr 2023

Process: 8032 Review Contact Documentation 22 Aug 2023

Process: 8050 Master Indemnity Register 29 Dec 2023

Process: 8053 Check The Whos Who 29 Dec 2023

Process: 8087 Research And Development Processing 20 Jan 2025 **Process: 8088** Research And Development Submission 20 Jan 2025

Process: 8086 Customer Climate Change Policys 06 Jan 2025

ID159363 Audit 10 Documentation Control Viamed

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 Post 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: 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: 7770 Audit 10 Documentation Control VST 08 Feb 2017

Process: 7863 Maintain Repair Codes List 05 Oct 2017

Process: 7922 Back Up Emily's Accounts Docs 04 Jan 2019

Process: 7987 Sync External Telephone Logs 07 Feb 2022

Process: 7992 COSHH Datasheet Reminders 07 Feb 2022

Process: 8001 Verification Stock Linked To Documents 08 Feb 2022

Process: 8029 Send Intercompany Invoices To Jean 12 Apr 2023

Process: 8032 Review Contact Documentation 22 Aug 2023

Process: 8039 Weee Report Due Vandagraph Annual 29 Dec 2023

Process: 8050 Master Indemnity Register 29 Dec 2023

Process: 8053 Check The Whos Who 29 Dec 2023

Process: 8087 Research And Development Processing 20 Jan 2025

Process: 8088 Research And Developement Submission 20 Jan 2025

ID159361

Audit 10 Documentation Control VST

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 Post 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: 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

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Process: 44 Secure Socket Level Certificate 16 Feb 2016			
December 7000 Charle Mahaita ICO December 24 Feb 2016			
Process: 5890 Check Website ISO Documents 24 Feb 2016			
Process: 7770 Audit 10 Documentation Control VST 08 Feb 2017			
Process: 7863 Maintain Repair Codes List 05 Oct 2017			
Process: 7922 Back Up Emily's Accounts Docs 04 Jan 2019			
Process: 7987 Sync External Telephone Logs 07 Feb 2022			
Process: 7992 COSHH Datasheet Reminders 07 Feb 2022			
Process: 8001 Verification Stock Linked To Documents 08 Feb 2022			
Process: 8029 Send Intercompany Invoices To Jean 12 Apr 2023			
Process: 8032 Review Contact Documentation 22 Aug 2023			
Process: 8039 Weee Report Due Vandagraph Annual 29 Dec 2023			
Process: 8050 Master Indemnity Register 29 Dec 2023			
Process: 8053 Check The Whos Who 29 Dec 2023			
Chart 27 Customer Complaints Chart 27			
Process: 7743 Customer Complaints Paper File 26 Sep 2016			
Audit 20 Process verification to Managment Viamed			
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 Viamed 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 Incorrect 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
ID85362	VM3COP27.02 Collecting Emails and Distributing Process: 10 Distribution Of Emails 16 Feb 2016
ID159471	Audit 18 Management Review Viamed 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: 7793 Management Meeting Warehouse 22 Nov 2016 Process: 6861 Management Meeting Review Weekly Meeting 09 Mar 2016 Process: 7834 Financial Review 20 Sep 2017 Process: 7834 Financial Review 20 Sep 2017 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: 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: 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 **Process: 7980** Review Gov Website For Applicable Required Standards

Process: 7980 Review Gov Website For Applicable Required Standards

ISO9001 15 Nov 2021

Process: 7972 ISO System Management Review Vst 26 Oct 2021

Process: 7977 Review The Agenda For The Management Review / Board

Meeting Prior To The Annual Meeting 11 Nov 2021

Process: 7978 Regulatory Requirements and Review of QC21 form template

11 Nov 2021

Process: 7979 Review The Template Of The QC 21 Form To Ensure It Is

Current And Valid 12 Nov 2021

Process: 7981 Review Process Updates For Risk To Systems 18 Nov 2021

Process: 8018 Wednesday Meeting 09 Aug 2022

Process: 8026 Automotive Competitor Price Review 10 Mar 2023

Process: 8025 Check We Do Not Require A EU European Representatives 09

Mar 2023

Process: 8036 Future Issues Review 19 Dec 2023

Process: 8041 Quarterly Sales And Marketing Meeting 29 Dec 2023

Process: 8072 Quartly Sales And Marketing Meeting Due 03 Jan 2024

Process: 8073 Quarterly Stock Meeting Due 03 Jan 2024

Process: 8074 Carbon Reduction Planning 26 Jan 2024

Process: 8094 Meeting With DL 16 May 2025

ID135771

VOP 13 Process Monitoring, System Reviews, Audits, Management

Reviews Analysis Data PMS Post Market

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 2016Process: 7723 Audit 10b Process Verification Viamed 24 Aug 2016Process: 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 2016Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016Process: 7729 Audit 19 Health And Saftey Viamed 24 Aug 2016

Process: 7730 Audit 20 Process Verification To Managment Viamed 24 Aug

2016

Process: 7731 Audit 21 Audit Of Audit Viamed 24 Aug 2016

Process: 7732 Audit 22 Post Market Survellance Viamed 24 Aug 2016

Process: 7733 Audit 23 Analysis Of Data Viamed 24 Aug 2016

Process: 6828

Process: 22 Company Policys 16 Feb 2016

Process: 7754

Process: 7763 Audit 02 Contract Review VST 08 Feb 2017

Process: 7765 Audit 05 Purchasing Suppliers 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: 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 Saftey VST 08 Feb 2017

Process: 7778 Audit 20 Process Verification To Managment VST 08 Feb 2017

Process: 7779 Audit 21 Audit Of Audit VST 08 Feb 2017

Process: 7780 Audit 22 Post Market Survellance 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

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: 7045 Responsibility Allocation : Design and Development 09 Mar

2016

Process: 38 Audits Up to Date and Confirm next years Audit schedule 16 Feb

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 Viamed 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: 7762 Audit 01 Picking Packing VST 08 Feb 2017 Process: 7764 Audit 03 Design Control VST 08 Feb 2017 Process: 7766 Audit 06 Calibration VST 08 Feb 2017

Process: 7770 Audit 10 Documentation Control VST 08 Feb 2017

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: 7830 Review Q.A. Failures Report 18 Sep 2017

Process: 7848 Review ISO Scopes 27 Sep 2017

Process: 7849 Review Product Failures New Codes 28 Sep 2017

Process: 7862 Review The Audit Calender Screen 04 Oct 2017

Process: 7877 Disaster Planning 21 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 Viamed 23 Oct 2017 **Process: 7886** Audit 18 Management Review Viamed 24 Oct 2017

Process: 7887 Audit 18 Management Review VST 24 Oct 2017

T TOO 1 11: 010 11 TY 1010 1001

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

Process: 7980 Review Gov Website For Applicable Required Standards

ISO9001 15 Nov 2021

Process: 7972 ISO System Management Review Vst 26 Oct 2021

Process: 7973 VST Product Performance - Customers 27 Oct 2021

Process: 7974 VST Product Performance - Suppliers 27 Oct 2021

Process: 7977 Review The Agenda For The Management Review / Board

Meeting Prior To The Annual Meeting 11 Nov 2021

Process: 7978 Regulatory Requirements and Review of QC21 form template

11 Nov 2021

Process: 7981 Review Process Updates For Risk To Systems 18 Nov 2021

Process: 8012 VAT Return Viamed Properties 06 Apr 2022

Process: 8014 Review VIAMED Product Feedback Positive 25 Jul 2022

Process: 8015 Review VST Product Feedback Positive 25 Jul 2022

Process: 8016 Review VIAMED Customer Feedback Positive 25 Jul 2022

Process: 8017 Review VST Customer Feedback Positive 25 Jul 2022

Process: 8018 Wednesday Meeting 09 Aug 2022

Process: 8019 Audit 04 Accounts And Finance VST 14 Sep 2022

Process: 8036 Future Issues Review 19 Dec 2023

Process: 8041 Quarterly Sales And Marketing Meeting 29 Dec 2023 **Process: 8072** Quartly Sales And Marketing Meeting Due 03 Jan 2024

Process: 8073 Quarterly Stock Meeting Due 03 Jan 2024

Process: 8089 Review Any Outstanding QC 21 Forms To Sign Off 07 Feb 2025

Process: 8094 Meeting With DL 16 May 2025

ID159433 Audit 05 Purchasing suppliers Viamed

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

Process: 7975 Arrange Teledyne Returns 03 Nov 2021 **Process: 7984** Check For Viking Invoices 19 Jan 2022

Process: 7991 Verification Purchasing Documentation 07 Feb 2022

Process: 8003 Verification Supplier Delivery Notes 17 Feb 2022

Process: 8030 Purchase Order Invoice Review 23 Jun 2023

Process: 8034 Purchase Order Invoice Review Stage 2 30 Nov 2023 **Process: 8039** Weee Report Due Vandagraph Annual 29 Dec 2023

Process: 8040 Weee Report Due Vandagraph Qtr 29 Dec 2023

Process: 8051 Purchase Order Log Viamed 29 Dec 2023

ID200924

VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier

Returns and Rejection

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

Process: 7975 Arrange Teledyne Returns 03 Nov 2021

Process: 7984 Check For Viking Invoices 19 Jan 2022

Process: 8009 Verification Stock Items And Locations 21 Feb 2022

Process: 7991 Verification Purchasing Documentation 07 Feb 2022

Process: 8002 Verification Todays Goods In 17 Feb 2022

Process: 8003 Verification Supplier Delivery Notes 17 Feb 2022

Process: 8030 Purchase Order Invoice Review 23 Jun 2023

Process: 8034 Purchase Order Invoice Review Stage 2 30 Nov 2023

Process: 8039 Weee Report Due Vandagraph Annual 29 Dec 2023

Process: 8040 Weee Report Due Vandagraph Qtr 29 Dec 2023

Process: 8052 Check Supplier Returns 29 Dec 2023

Process: 8051 Purchase Order Log Viamed 29 Dec 2023

ID91486

VOP 27 Software Validation

Process: 46 Responsibility Allocation : Backup Server Status 16 Feb 2016

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 Incorrect 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 Viamed 26 Oct 2017

Process: 8013 Software Validation Test Email System 29 Apr 2022

Process: 8079 Audit 27 Software Validation VST 10 Jul 2024

Process: 8083 Software Validation SRS To Nonconformance 31 Oct 2024

ID156701 Audit 27

Audit 27 Software Validation Viamed

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 Incorrect 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 Viamed 26 Oct 2017

Process: 7951 Server Review 05 Mar 2020

Process: 8013 Software Validation Test Email System 29 Apr 2022

Process: 8083 Software Validation SRS To Nonconformance 31 Oct 2024

ID173558

Audit 03 Design Control Viamed

Process: 7716 Audit 03 Design Control Viamed 24 Aug 2016

Process: 42 Responsibility Allocation : Design Documentation 16 Feb 2016

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: 7764** Audit 03 Design Control VST 08 Feb 2017

Process: 7919 Send Debtors Overview To Derek 06 Dec 2018

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

ID158752 Audit 23 Analysis of Data Viamed

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: 7862 Review The Audit Calender Screen 04 Oct 2017

Process: 7930 Review Flow Of Data 12 Mar 2019

Process: 7969 Weee Waste Reporting 23 Aug 2021

ID151817

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 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 : Eye Tests 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 Responsibilitys 17 Aug 2016

Process: 7837 Review External Parties Influencing The QMS VST / Viamed

23 Sep 2017

Process: 29 Responsibility Allocation: CMDCAS Updates And Licences 16

Feb 2016

Process: 7848 Review ISO Scopes 27 Sep 2017

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 Process: 7982 Check There Are No Changes To Employment Law 21 Nov 2021 **Process: 7983** To Check On Line And See If There Have Been Any Changes To Gdpr We Need To Be Aware Of. 21 Nov 2021 **Process: 8054** Team Building Event - June 29 Dec 2023 **Process: 8055** Christmas/Team Building Event - December 29 Dec 2023 **Process: 8067** Training Refresh Issues To Send / Questions To Write 03 Jan 2024 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 ID119029 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

ID77875

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 Post 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: 21 Office Sales Projects 16 Feb 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: 5897 Responsibility Allocation : Franking Mail 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 - Priority 8s 21

Apr 2016

Process: 7699 Shred Sensitive Paperwork In JL Office 19 May 2016

Process: 7705 Checking For Uploaded Files 08 Jun 2016

Process: 7709 Delivered not Invoiced 28 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: 7872 Embargo Countries NOT Allowed To Sell To 16 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: 7957 Warehouse Requests 29 May 2020

Process: 7959 Audit 16 Sales And Marketing Viamed 28 Sep 2020

Process: 7970 Proforma And Quote Chasing Ryan 31 Aug 2021 **Process: 7971** Proforma And Quote Chasing U.K. 31 Aug 2021

Process: 7988 Verification Contact Details Internal CRM 07 Feb 2022

Process: 7989 Verification Contact Details Accounts 07 Feb 2022 **Process: 7990** Verification Invoice Details Accounts 07 Feb 2022

Process: 8020 Checking Proformas And Quotes Vandagraph To The Bank 05

Dec 2022

Process: 8023 Vandagraph Check Shopify Order Delivery Notifications 17

Feb 2023

Process: 8026 Automotive Competitor Price Review 10 Mar 2023

Process: 8033 Sales Forecasts 30 Oct 2023

Process: 8061 Reconcile Invoices In B2B Router 03 Jan 2024

Process: 8093 Review Special Price 15 May 2025

Process: 8097 **Review Shopify Delivery Notifications - Vandagraph 30 Oct

2025

ID163469 Audit 02 Contract Review and Sales Order Processing Viamed

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: 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: 5897 Responsibility Allocation : Franking Mail 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 - Priority 8s 21

Apr 2016

Process: 7709 Delivered not Invoiced 28 Jun 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

Process: 7970 Proforma And Quote Chasing Ryan 31 Aug 2021

Process: 7971 Proforma And Quote Chasing U.K. 31 Aug 2021

Process: 8005 Verification Of SRS Information added 17 Feb 2022 **Process: 7988** Verification Contact Details Internal CRM 07 Feb 2022

Process: 7989 Verification Contact Details Accounts 07 Feb 2022

Process: 8020 Checking Proformas And Quotes Vandagraph To The Bank 05

Dec 2022

Process: 8023 Vandagraph Check Shopify Order Delivery Notifications 17

Feb 2023

Process: 8027 Update Pricing For Viamed Shopify 11 Apr 2023

Process: 8028 Viamed Shopify Sales Report Export 11 Apr 2023

Process: 8033 Sales Forecasts 30 Oct 2023

Process: 8061 Reconcile Invoices In B2B Router 03 Jan 2024

Process: 8071 Checked Repair Quotes Have Been Sent To Customers 03 Jan

139 of 158

2024

Process: 8080 Review Back To Stock Report On Shopify 10 Sep 2024

Process: 8086 Customer Climate Change Policys 06 Jan 2025

ID132118

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

Process: 7954 Vandagraph Email Of Invoices 26 May 2020

Process: 7979 Review The Template Of The QC 21 Form To Ensure It Is

Current And Valid 12 Nov 2021

Process: 8068 Request Feedback From Unique Customer For 2 Months Prior

03 Jan 2024

Process: 8070 Website Order VM-2160 VET Feedback 03 Jan 2024

ID137933

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

Process: 7967 VST Stock Count For End April 01 Jul 2021

Process: 7969 Weee Waste Reporting 23 Aug 2021

Process: 8006 Verification Warehouse Unidentified Stock 17 Feb 2022

Process: 8008 Verification Warehouse Hand Sanitiser 21 Feb 2022

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Process: 8009 Verification Stock Items And Locations 21 Feb 2022

Process: 8010 Verification Of Ebay Stock 21 Feb 2022 **Process: 8011** Verification Of Demo Stock 21 Feb 2022

Process: 7996 Verification Repairs Older Repairs 07 Feb 2022

Process: 8002 Verification Todays Goods In 17 Feb 2022

Process: 8004 Verification Of Non Conforming Products 17 Feb 2022

Process: 8024 Discontinue/Supersede Stock 01 Mar 2023

Process: 8060 Sealant, Glues, Greases, Sprays, Gases And Tapes You Use In Production, Service And Repairs For Viamed And VST Phils Issue 03 Jan

2024

ID159461 Audit 16 Sales and Marketing Viamed

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 2019Process: 7926 Sales Forecasts Export 22 Jan 2019Process: 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

Process: 8031 Tenders Review UN 02 Aug 2023

Process: 8046 Shopify Add Words 29 Dec 2023

Process: 8056 Add Calendar To Order 29 Dec 2023

Process: 8062 Vandagraph Shopify Payouts Report 03 Jan 2024

Process: 8068 Request Feedback From Unique Customer For 2 Months Prior

03 Jan 2024

Process: 8049 Book Medica 29 Dec 2023

Process: 8057 Emergency Services Show 29 Dec 2023

Process: 8058 Preparation For Medica 03 Jan 2024

Process: 8059 Preparation For Medica Leaflets 03 Jan 2024 **Process: 8063** Send Calendars To Sylvia Gallagher 03 Jan 2024

Process: 8065 Review Shopify Website For Missing Images 03 Jan 2024

Process: 8066 Review Search Terms - Shopify 03 Jan 2024 **Process: 8069** Viamed Shopify: Office Hours 03 Jan 2024

Process: 8075 Tenders Review UK 14 Feb 2024 **Process: 8093** Review Special Price 15 May 2025

Process: 8095 Medica Pallet - Return Contents To Stock/exhibition 21 May

2025

ID181426 **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

Process: 7976 Decontamination Of Incoming Products And Repairs 08 Nov

2021

Process: 8092 Sensor Recycle / Depletions Logging 06 May 2025

ID103501 VM3COP20.01 Post In Distributing the Post

Process: 11 Distribution Of Post 16 Feb 2016

Process: 5882 Responsibility Allocation : Send Post To Humanmed 24 Feb

2016

ID162725 Audit 08 Training, Competence and Human Resources Viamed

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 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 : Eye Tests 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: 38 Audits Up to Date and Confirm next years Audit schedule 16 Feb

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

Process: 7982 Check There Are No Changes To Employment Law 21 Nov

2021

Process: 7983 To Check On Line And See If There Have Been Any Changes

To Gdpr We Need To Be Aware Of. 21 Nov 2021

Process: 8054 Team Building Event - June 29 Dec 2023

Process: 8055 Christmas/Team Building Event - December 29 Dec 2023 **Process: 8067** Training Refresh Issues To Send / Questions To Write 03 Jan

2024

Process: 8082 HSE Workplace Safety Environment And Harassment Risk

Assessment Questionnaire 23 Oct 2024

Process: 8081 Anti Harassment Awareness And Prevention 18 Oct 2024

ID159483

Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Viamed

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 2017Process: 7836 Central Heating For Winter 20 Sep 2017Process: 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 **Process: 7982** Check There Are No Changes To Employment Law 21 Nov 2021 **Process: 7999** Building Risk Assesments 08 Feb 2022 **Process: 8038** Defrost Fridge / Freezer 29 Dec 2023 **Process: 8039** Weee Report Due Vandagraph Annual 29 Dec 2023 **Process: 8043** Turn Off Outside Tap On The Warehouse 29 Dec 2023 **Process: 8045** Radiators - Bleed Radiators In Vandagraph Room In Warehouse And Loft In Offices 29 Dec 2023 **Process: 8047** Electric Testing 29 Dec 2023 Process: 8048 Workshop Toilet Is To Be Cleaned And Rubbish To Be Binned 29 Dec 2023 **Process: 8044** PAT Test 29 Dec 2023 VM3COP02.02 VST Company Responsibilitys organisation chart ID29373 structure **Process: 5877** Review Company Data 17 Feb 2016 ID159485 **Audit 21 Audit of Audit Viamed** 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 ID186382 Audit 22 Post Market Survellance Viamed Process: 7732 Audit 22 Post Market Survellance Viamed 24 Aug 2016 Process: 43 Responsibility Allocation: Product Post Market Survelance 16 Feb 2016 Process: 7780 Audit 22 Post Market Survellance VST 08 Feb 2017 Process: 6889 Responsibility Allocation : Post Market Surveilance 09 Mar 2016 **Process: 7809** Pro-Active Marketing 06 Jun 2017 **Process: 7810** Research Activities 06 Jun 2017 **Process: 5863** Responsibility Allocation : Sales Meetings UK 17 Feb 2016 **Process: 5864** Responsibility Allocation : Sales Meeting EX 17 Feb 2016 Process: 7973 VST Product Performance - Customers 27 Oct 2021 **Process: 7974** VST Product Performance - Suppliers 27 Oct 2021

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Process: 8014 Review VIAMED Product Feedback Positive 25 Jul 2022

Process: 8016 Review VIAMED Customer Feedback Positive 25 Jul 2022

Process: 8015 Review VST Product Feedback Positive 25 Jul 2022

Process: 8017 Review VST Customer Feedback Positive 25 Jul 2022 **Process: 8070** Website Order VM-2160 VET Feedback 03 Jan 2024

	Process: 8076 Medica Review 21 Feb 2024
ID126137	Viamed Management Review Blank Minutes 20xx
	Process: 7846 ISO System Management Review Viamed 26 Sep 2017
ID74728	QC 21 Non Conformance Form
	Process: 7138 Non Conformance Issues Any New QC21 Forms 09 Mar 2016
	Process: 7979 Review The Template Of The QC 21 Form To Ensure It Is
	Current And Valid 12 Nov 2021
ID166222	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 Ou
	UPS Account 18 Feb 2016
ID184932	Audit 07 Handling and Storage Viamed
	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 produc
	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

Process: 8008 Verification Warehouse Hand Sanitiser 21 Feb 2022

Process: 8002 Verification Todays Goods In 17 Feb 2022

Process: 8004 Verification Of Non Conforming Products 17 Feb 2022

Process: 8024 Discontinue/Supersede Stock 01 Mar 2023

Process: 8060 Sealant, Glues, Greases, Sprays, Gases And Tapes You Use In Production, Service And Repairs For Viamed And VST Phils Issue 03 Jan

2024

ID168580

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

Process: 7998 Verification Calibrated Equipment 08 Feb 2022

Process: 8044 PAT Test 29 Dec 2023

ID191692

Audit 15 Production Viamed

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

Process: 8000 Verification Production Paperwork 08 Feb 2022

Process: 8037 Projects / Products HSE Requirements 29 Dec 2023

Process: 8064 Production Of JJCCR Cables 03 Jan 2024

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: 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

Process: 7928 Fire Test Points Checking 21 Feb 2019 **Process: 7999** Building Risk Assesments 08 Feb 2022

Process: 8082 HSE Workplace Safety Environment And Harassment Risk

Assessment Questionnaire 23 Oct 2024

Process: 8081 Anti Harassment Awareness And Prevention 18 Oct 2024

ID174218

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

Process: 8038 Defrost Fridge / Freezer 29 Dec 2023

Process: 8043 Turn Off Outside Tap On The Warehouse 29 Dec 2023

Process: 8045 Radiators - Bleed Radiators In Vandagraph Room In

Warehouse And Loft In Offices 29 Dec 2023 **Process: 8047** Electric Testing 29 Dec 2023

Process: 8048 Workshop Toilet Is To Be Cleaned And Rubbish To Be Binned

29 Dec 2023

Process: 8044 PAT Test 29 Dec 2023

ID137919

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

Process: 7985 OverDue Servicing 03 Feb 2022

Process: 7993 Verification Warranty Repairs Customer Approval 07 Feb

2022

Process: 7994 Verification Repairs Paperwork Completed 07 Feb 2022

Process: 7995 Verification Visual Check Repair Shelf 07 Feb 2022

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Process: 7996 Verification Repairs Older Repairs 07 Feb 2022

Process: 7997 Verification Repair Qa Reports 07 Feb 2022

Process: 8005 Verification Of SRS Information added 17 Feb 2022

Process: 8022 Vandagraph Repair Review 06 Feb 2023

Process: 8071 Checked Repair Quotes Have Been Sent To Customers 03 Jan

2024

ID166168

Audit 09 Goods Inward and Product Identity Viamed

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

Process: 7967 VST Stock Count For End April 01 Jul 2021

Process: 7976 Decontamination Of Incoming Products And Repairs 08 Nov

2021

Process: 8006 Verification Warehouse Unidentified Stock 17 Feb 2022

Process: 8009 Verification Stock Items And Locations 21 Feb 2022

Process: 8010 Verification Of Ebay Stock 21 Feb 2022

Process: 8011 Verification Of Demo Stock 21 Feb 2022

Process: 8092 Sensor Recycle / Depletions Logging 06 May 2025

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
	Process: 8000 Verification Production Paperwork 08 Feb 2022
İ	Process: 8037 Projects / Products HSE Requirements 29 Dec 2023
	Process: 8064 Production Of JJCCR Cables 03 Jan 2024
D165205	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
D165199	VM3COP20.30 UK Order Processing
	Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017
D22266	VM3COP03.07 Humanmed Order Checking
1022200	Process: 7 Responsibility Allocation : Checking Of Sales Orders 16 Feb 2016
	Process: 7734 Responsibility Allocation : Humanmed Order Processing 25
	Aug 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
ID173579	Audit 01 Picking packing Viamed
	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: 7796 Review Franking Label Errors 08 May 2017
	Process: 7796 Review Franking Label Errors 08 May 2017

	Process: 7860 Goods Out Picking 03 Oct 2017
	Process: 8027 Update Pricing For Viamed Shopify 11 Apr 2023
ID34889	VM3COP20.32 Order Checking
	Process: 7825 Responsibility Allocation : Order Picking 06 Sep 2017
ID166158	Audit 11 Repairs, Servicing and Returns Viamed
	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
	Process: 7993 Verification Warranty Repairs Customer Approval 07 Feb
	2022
	Process: 7994 Verification Repairs Paperwork Completed 07 Feb 2022
	Process: 7995 Verification Visual Check Repair Shelf 07 Feb 2022
	Process: 7996 Verification Repairs Older Repairs 07 Feb 2022
	Process: 7997 Verification Repair Qa Reports 07 Feb 2022
	Process: 8022 Vandagraph Repair Review 06 Feb 2023
	Process: 8052 Check Supplier Returns 29 Dec 2023
ID69812	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
ID04044	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
ID21314	Process C020
	Process: 6828

ID159455

Audit 14 Complaints and Corrective Actions Viamed

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 Viamed 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

Process: 7264 Responsibility Allocation : VST Management Meeting Non

Conformance Issues 09 Mar 2016

Process: 8089 Review Any Outstanding QC 21 Forms To Sign Off 07 Feb 2025

ID159427

Audit 04 Accounts and Finance Viamed

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 Viamed 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

ID181242

ID137913

ID73132

ID17070

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 Process: 7968 Shred CC Slips 06 Aug 2021 **Process: 7984** Check For Viking Invoices 19 Jan 2022 **Process: 8007** Verification Credit Notes 17 Feb 2022 Process: 7986 Check Creditors 03 Feb 2022 **Process: 7990** Verification Invoice Details Accounts 07 Feb 2022 Process: 8012 VAT Return Viamed Properties 06 Apr 2022 **Process: 8019** Audit 04 Accounts And Finance VST 14 Sep 2022 Process: 8021 Check Xero Bank For The Year To The Barclays Bank Account 06 Jan 2023 Process: 8035 USA Tax Book Sales 14 Dec 2023 **Process: 8042** PAYE Needs Paying URGENT 29 Dec 2023 Process: 8077 Download HMRC Reports 18 Jun 2024 Process: 8085 Stock Figure - Correct Xero To Intrastats 16 Dec 2024 Process: 8090 Viamed Check And Allocate Debtors. Ready For Accountants. 13 Feb 2025 **Process: 8096** Review Contracts Advance Renewal 17 Jun 2025 **Process: 8098** Carry Out The HMRC Slavery Assessment 10 Oct 2025 Audit 12 CE Files Viamed 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 **VOP 15 Data and Information Analysis** Process: 8074 Carbon Reduction Planning 26 Jan 2024 VM3COP20.29 Checking the Purchase Order Log **Process: 5850** Purchase Order Log 17 Feb 2016 VM3COP27.34 Sending Purchase Orders to Suppliers **Process: 7707** Send Purchase Orders To Suppliers 13 Jun 2016

ID186878	Audit 06 Calibration VIAMED
	Process: 7718 Audit 06 Calibration Viamed 24 Aug 2016
	Process: 7048 Control of monitoring and measuring devices 09 Mar 2016
	Process: 7091 Calibration Index 09 Mar 2016
	Process: 7766 Audit 06 Calibration VST 08 Feb 2017
	Process: 7998 Verification Calibrated Equipment 08 Feb 2022
ID164829	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
ID159493	Audit 24 Service Logs Viamed
	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
	Process: 7985 OverDue Servicing 03 Feb 2022
ID24509	VM3COP20.27 Annual Services for Resuscitation Cabinets
	Process: 5857 Customer Service Logs 17 Feb 2016
ID75624	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
ID159465	Audit 17 Internal Audits Viamed
	Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016
	Process: 7728 Audit 17 Internal Audits Viamed 24 Aug 2016 Process: 7776 Audit 17 Internal Audits VST 08 Feb 2017

ID124938

VOP 10 Non Conformance, Corrective and Preventive Actions

Process: 7199 Non Conformities Review Viamed 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

Process: 7264 Responsibility Allocation : VST Management Meeting Non

Conformance Issues 09 Mar 2016