

Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015

13 Oct 2022 Revision:1665672761 ID101068

Audit Links / Schedule

Section	VOPS / VM3COPS	Audits Attached (Process IDs)
4 Context of the organization		
4	QMS Route Map VST Ltd ISO9001_2015 VST ISO 9001:2015 Scope Need Risks and Expectations of External Parties VST	
4.1	Need Risks and Expectations of External Parties VST VOP 24 Needs, Risks and Expectations of External Parties	Audit 18 Management Review (7886 Oct 7887 Oct)
4.2	Need Risks and Expectations of External Parties VST VOP 24 Needs, Risks and Expectations of External Parties	Audit 18 Management Review (7886 Oct 7887 Oct)
4.3	VST ISO 9001:2015 Scope VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records	Audit 18 Management Review (7886 Oct 7887 Oct)
4.4	QMS Route Map VST Ltd ISO9001_2015	Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
4.4.1		Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
4.4.2	VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun)
5 Leadership		
5		
5.1		
5.1.1	VM3COP00.00 Viamed Quality Statement policy and objectives VM3COP02.02 Viamed Company Responsibilitys organisation chart structure VOP 18 Maintenance Building, Fabric and Infrastructure VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun) Audit 18 Management Review (7886 Oct 7887 Oct) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
5.1.2	VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd VOP 03 Contract Review, Enquires, Office Processes VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	Audit 01 Picking packing (7714 Jan 7762 Jan 7860 Jan) Audit 02 Contract Review and Sales Order Processing (7715 Sep 7763 Sep) Audit 16 Sales and Marketing ()
5.2		
5.2.1	VM3COP00.00 Viamed Quality Statement policy and objectives	Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
5.2.2	VOP 01 Documentation and Records, Control, Creation,	Audit 10 Documentation Control (7722 Jun 15 Mar

	Storage, Retrieval, Revision Control and Online Records	7770 Jun)
5.3	VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Audit 20 Process verification to Managment (7730 Nov 7778 Nov) Audit 21 Audit of Audit (7731 Dec 7779 Dec 7862 Dec)

6 Planning

6		
6.1		
6.1	Need Risks and Expectations of External Parties VST VOP 24 Needs, Risks and Expectations of External Parties	Audit 18 Management Review (7886 Oct 7887 Oct)
6.1.2		Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr) Audit 18 Management Review (7886 Oct 7887 Oct)
6.2		
6.2.1	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
6.2.2		Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
6.3	VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun)

7 Support

7		
7.1		
7.1.1 General		Audit 18 Management Review (7886 Oct 7887 Oct)
7.1.2	VOP 12 Training	Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
7.1.3	VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment VOP 18 Maintenance Building, Fabric and Infrastructure VOP 06 Measurement Control Viamed VST, Calibration, QA Stock	Audit 15 Production (7727 May 7775 May) Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 19 Health and Safety, Working Conditions and Building Fabric Issues (7729 Aug 7777 Aug)
7.1.4	VOP 12 Training VOP 16 Health and Safety, Company Personnel Manual VOP 18 Maintenance Building, Fabric and Infrastructure VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Audit 19 Health and Safety, Working Conditions and Building Fabric Issues (7729 Aug 7777 Aug) Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
7.1.5		
7.1.5.1	VOP 06 Measurement Control Viamed VST, Calibration, QA Stock	Audit 06 Calibration (7718 May 7766 May) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
7.1.5.2	VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment VOP 06 Measurement Control Viamed VST, Calibration, QA Stock VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	Audit 06 Calibration (7718 May 7766 May) Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun)
7.1.6		Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr) Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun)

7.2	VOP 12 Training VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Audit 19 Health and Safety, Working Conditions and Building Fabric Issues (7729 Aug 7777 Aug) Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun)
7.3	VOP 12 Training VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Audit 19 Health and Safety, Working Conditions and Building Fabric Issues (7729 Aug 7777 Aug) Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun)
7.4		Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun)
7.5		
7.5.1	VM3COP00.00 Viamed Quality Statement policy and objectives VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
7.5.2	VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records VOP 10 Non Conformance, Corrective and Preventive Actions	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 23 Analysis of Data (7733 Jul 7781 Jul 7071 Apr 7862 Dec)
7.5.3	VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records VOP 10 Non Conformance, Corrective and Preventive Actions	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 23 Analysis of Data (7733 Jul 7781 Jul 7071 Apr 7862 Dec)
7.5.3.1		Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
7.5.3.2		Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)

8 Operation

8		
8.1	VOP 08 Production, Reworks, New Production VM3COP27.11 Performing a Technical File PMS and risk assessment	Audit 03 Design Control (7716 Jan 7764 Jan) Audit 22 Post Market Surveillance (7732 Apr 7780 Apr) Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 23 Analysis of Data (7733 Jul 7781 Jul 7071 Apr 7862 Dec) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.2		
8.2.1	VOP 09 Repairs and Servicing VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd VOP 03 Contract Review, Enquires, Office Processes	Audit 22 Post Market Surveillance (7732 Apr 7780 Apr) Audit 11 Repairs, Servicing and Returns (7724 Jul 7772 Jul) Audit 02 Contract Review and Sales Order Processing (7715 Sep 7763 Sep)
8.2.2	VOP 17 Design Research and Development VOP 03 Contract Review, Enquires, Office Processes	Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr) Audit 02 Contract Review and Sales Order Processing (7715 Sep 7763 Sep) Audit 16 Sales and Marketing ()
8.2.3		
8.2.3.1	VOP 03 Contract Review, Enquires, Office Processes	Audit 02 Contract Review and Sales Order Processing (7715 Sep 7763 Sep)
8.2.3.2	VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records	Audit 22 Post Market Surveillance (7732 Apr 7780 Apr) Audit 02 Contract Review and Sales Order Processing (7715 Sep 7763 Sep)

8.2.4	VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records VOP 03 Contract Review, Enquires, Office Processes	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 02 Contract Review and Sales Order Processing (7715 Sep 7763 Sep)
8.3		
8.3.1 General	VOP 17 Design Research and Development	Audit 03 Design Control (7716 Jan 7764 Jan)
8.3.2	VOP 17 Design Research and Development	Audit 03 Design Control (7716 Jan 7764 Jan) Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr)
8.3.3	VOP 17 Design Research and Development	Audit 03 Design Control (7716 Jan 7764 Jan) Audit 22 Post Market Surveillance (7732 Apr 7780 Apr) Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr)
8.3.4	VOP 17 Design Research and Development	Audit 03 Design Control (7716 Jan 7764 Jan) Audit 22 Post Market Surveillance (7732 Apr 7780 Apr) Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun)
8.3.5	VOP 17 Design Research and Development	Audit 03 Design Control (7716 Jan 7764 Jan) Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun)
8.3.6	VOP 17 Design Research and Development	Audit 03 Design Control (7716 Jan 7764 Jan) Audit 22 Post Market Surveillance (7732 Apr 7780 Apr) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)
8.4		
8.4.1	VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection	Audit 05 Purchasing suppliers (7717 Sep 7765 Sep) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.4.2	VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection	Audit 05 Purchasing suppliers (7717 Sep 7765 Sep)
8.4.3	VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection	Audit 05 Purchasing suppliers (7717 Sep 7765 Sep)
8.5		
8.5.1	VOP 22 Picking and Packing Dispatch and Goods Out VOP 08 Production, Reworks, New Production VOP 06 Measurement Control Viamed VST, Calibration, QA Stock VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement VOP 27 Software Validation VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Audit 01 Picking packing (7714 Jan 7762 Jan 7860 Jan) Audit 03 Design Control (7716 Jan 7764 Jan) Audit 09 Goods Inward and Product Identity (7721 Mar 7769 Mar) Audit 15 Production (7727 May 7775 May) Audit 06 Calibration (7718 May 7766 May) Audit 24 Service Logs (7889 Aug) Audit 08 Training, Competence and Human Resources (7720 Jun 7768 Jun) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.5.2	VOP 09 Repairs and Servicing VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection	Audit 09 Goods Inward and Product Identity (7721 Mar 7769 Mar) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.5.3	VOP 09 Repairs and Servicing VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection	Audit 09 Goods Inward and Product Identity (7721 Mar 7769 Mar) Audit 11 Repairs, Servicing and Returns (7724 Jul 7772 Jul) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.5.4	VM3COP27.51 Incoming / Goods in Contamination Control VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	Audit 09 Goods Inward and Product Identity (7721 Mar 7769 Mar) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.5.5	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market	Audit 22 Post Market Surveillance (7732 Apr 7780 Apr)

		Audit 20 Process verification to Managment (7730 Nov 7778 Nov) Audit 14 Complaints and Corrective Actions (7726 Nov 7774 Nov)
8.5.6		Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr)
8.6	VOP 22 Picking and Packing Dispatch and Goods Out	Audit 09 Goods Inward and Product Identity (7721 Mar 7769 Mar) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.7		
8.7.1	VOP 06 Measurement Control Viamed VST, Calibration, QA Stock VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	Audit 09 Goods Inward and Product Identity (7721 Mar 7769 Mar) Audit 05 Purchasing suppliers (7717 Sep 7765 Sep) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
8.7.2		Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)

9 Performance evaluation

9		
9.1		
9.1.1	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market VOP 10 Non Conformance, Corrective and Preventive Actions	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 07 Handling and Storage (7719 Apr 7767 Apr)
9.1.2	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market	Audit 22 Post Market Surveillance (7732 Apr 7780 Apr) Audit 14 Complaints and Corrective Actions (7726 Nov 7774 Nov)
9.1.3	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection	Audit 22 Post Market Surveillance (7732 Apr 7780 Apr)
9.2		
9.2.1	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market	Audit 20 Process verification to Managment (7730 Nov 7778 Nov) Audit 17 Internal Audits (7728 Dec 7776 Dec) Audit 21 Audit of Audit (7731 Dec 7779 Dec 7862 Dec)
9.2.2	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 18 Management Review (7886 Oct 7887 Oct) Audit 21 Audit of Audit (7731 Dec 7779 Dec 7862 Dec)
9.3		
9.3.1	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market	Audit 18 Management Review (7886 Oct 7887 Oct)
9.3.2	VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market	Audit 18 Management Review (7886 Oct 7887 Oct)
9.3.3		Audit 18 Management Review (7886 Oct 7887 Oct) Audit 20 Process verification to Managment (7730 Nov 7778 Nov)

1 Improvement

10		
10.1	VOP 10 Non Conformance, Corrective and Preventive Actions	Audit 14 Complaints and Corrective Actions (7726 Nov 7774 Nov)

10.2	VOP 10 Non Conformance, Corrective and Preventive Actions	Audit 14 Complaints and Corrective Actions (7726 Nov 7774 Nov)
10.2.1	VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd VOP 10 Non Conformance, Corrective and Preventive Actions	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 12 CE Files (7725 Mar 7773 Mar 7071 Apr) Audit 14 Complaints and Corrective Actions (7726 Nov 7774 Nov)
10.2.2	VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd VOP 10 Non Conformance, Corrective and Preventive Actions	Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun)
10.3		Audit 10 Documentation Control (7722 Jun 15 Mar 7770 Jun) Audit 18 Management Review (7886 Oct 7887 Oct)

Month	Description	TaskID	ProcessID	Date
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Jan

Jan	ID22 : Audit 03 Design Control Viamed	TaskID 22	ProcessID 7716
Jan	ID24 : Audit 01 Picking Packing Viamed	TaskID 24	ProcessID 7860
Jan	ID193 : Audit 03 Design Control VST	TaskID 193	ProcessID 7764
Jan	ID194 : Audit 01 Picking Packing VST	TaskID 194	ProcessID 7762

Feb

Feb	ID821 : Audit 27 Software Validation	TaskID 821	ProcessID 7892
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Mar

Mar	ID170 : Audit 09 Goods Inward And Product Identity Viamed	TaskID 170	ProcessID 7721
Mar	ID16 : Audit 12 CE Files Viamed	TaskID 16	ProcessID 7725
Mar	ID174 : Audit 09 Goods Inward And Product Identity VST	TaskID 174	ProcessID 7769
Mar	ID176 : Audit 12 CE Files VST	TaskID 176	ProcessID 7773

Apr

Apr	ID14 : Audit 22 Post Market Surveillance Viamed	TaskID 14	ProcessID 7732
Apr	ID25 : Audit 07 Handling And Storage Viamed	TaskID 25	ProcessID 7719
Apr	ID178 : Audit 07 Handling And Storage VST	TaskID 178	ProcessID 7767
Apr	ID180 : Audit 22 Post Market Surveillance VST	TaskID 180	ProcessID 7780

May

May	ID20 : Audit 06 Calibration Viamed	TaskID 20	ProcessID 7718
May	ID28 : Audit 15 Production Viamed	TaskID 28	ProcessID 7727

May	ID175 : Audit 15 Production VST	TaskID 175	ProcessID 7775
May	ID182 : Audit 06 Calibration VST	TaskID 182	ProcessID 7766
Jun			
Jun	ID10 : Audit 08 Training Viamed	TaskID 10	ProcessID 7720
Jun	ID27 : Audit 10 Documentation Control Viamed	TaskID 27	ProcessID 7722
Jun	ID183 : Audit 10 Documentation Control VST	TaskID 183	ProcessID 7770
Jun	ID184 : Audit 08 Training VST	TaskID 184	ProcessID 7768
Jul			
Jul	ID43 : Audit 23 Analysis Of Data Viamed	TaskID 43	ProcessID 7733
Jul	ID171 : Audit 11 Repairs And Service Viamed	TaskID 171	ProcessID 7724
Jul	ID179 : Audit 11 Repairs And Service VST	TaskID 179	ProcessID 7772
Jul	ID185 : Audit 23 Analysis Of Data VST	TaskID 185	ProcessID 7781
Aug			
Aug	ID13 : Audit 19 Health And Saftey Viamed	TaskID 13	ProcessID 7729
Aug	ID186 : Audit 19 Health And Saftey VST	TaskID 186	ProcessID 7777
Aug	ID288 : Audit 24 Due Servicing	TaskID 288	ProcessID 7889
Sep			
Sep	ID36 : Audit 02 Contract Review Viamed	TaskID 36	ProcessID 7715
Sep	ID37 : Audit 05 Purchasing Suppliers Viamed	TaskID 37	ProcessID 7717
Sep	ID187 : Audit 02 Contract Review VST	TaskID 187	ProcessID 7763
Sep	ID190 : Audit 05 Purchasing Suppliers VST	TaskID 190	ProcessID 7765
Oct			
Oct	ID21 : Audit 18 Management Review Viamed	TaskID 21	ProcessID 7886
Oct	ID188 : Audit 18 Management Review VST	TaskID 188	ProcessID 7887
Nov			
Nov	ID30 : Audit 14 Complaints And Corrective Actions Viamed	TaskID 30	ProcessID 7726
Nov	ID172 : Audit 20 Process Verification To Managment Viamed	TaskID 172	ProcessID 7730
Nov	ID181 : Audit 20 Process Verification To Managment VST	TaskID 181	ProcessID 7778

Nov	ID189 : Audit 14 Complaints And Corrective Actions VST	TaskID 189	ProcessID 7774
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Dec

Dec	ID11 : Audit 17 Internal Audits Viamed	TaskID 11	ProcessID 7728
Dec	ID173 : Audit 21 Audit Of Audit Viamed	TaskID 173	ProcessID 7862
Dec	ID191 : Audit 17 Internal Audits VST	TaskID 191	ProcessID 7776
Dec	ID192 : Audit 21 Audit Of Audit VST	TaskID 192	ProcessID 7779