

Management Review Report

Viamed

Role: Audits

Report Date: 14 May 2026

Index

1. Audits (ID #43)
2. **Conclusion / Executive Summary**

Task Completion History - Colour Key

Colour coding in the 'Days to Complete' column reflects performance, not formal sign-off status (some auto-issue tasks never receive formal investigation sign-off).

Green	Completed in 14 days or less (good)
Yellow	Completed in 15 - 60 days (acceptable)
Orange	Completed in over 60 days (slow)
Red	Outstanding - not yet completed (age shown)

Role: Audits (ID #43)

Reports To: ISO and Compliance Controller ? Managing Director ? Share Holder

Assigned Employees: Derek Lamb, Helen Lamb, Auditor, Derek Lamb, Derek Lamb, Derek Lamb, Helen Lamb, Helen Lamb, Helen Lamb, Auditor, Auditor, Auditor

Processes Assigned: 50 (50 active, 0 responsibility-only)

Role Risk Indicators - Audits

- 50 linked processes
- No overdue rolling tasks
- 2 processes not reviewed >24 months
- 1 processes with only one trained user
- 5 processes missing measurable objective
- 4 processes with no audit configured

Dependency / Single-Point-of-Failure Risk

- Helen Lamb linked to 98% (49 of 50) of role processes - single point of failure risk
- Derek Lamb linked to 100% (50 of 50) of role processes - single point of failure risk
- 1 process(es) have only 1 trained employee - no backup coverage

Process ID #7714 — Audit 01 Picking Packing Viamed

Last Reviewed: 16 Feb 2026 by Derek Lamb

Management Review

Viamed - Audits

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 01 Picking Packing Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.4.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 7.2.2
- VIAMED ISO 13485:2008 Manual: 7.2.2.B
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.2.B
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Management Review

Viamed - Audits

- Customer

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 01 Picking packing Viamed (Doc ID: 173579)
- Audit 01 Picking packing VST (Doc ID: 173583)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #24

Subject: Audit 01 Picking Packing Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

BEFORE starting Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
384634	Audit 01 Picking Packing Viamed (24)	01 Jan 2026	27 Feb 2026	57 days	Derek Lamb
350890	Audit 01 Picking Packing Viamed (24)	01 Jan 2025	27 Feb 2026	422 days	Derek Lamb

Process ID #7762 — Audit 01 Picking Packing VST

Management Review

Viamed - Audits

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 01 Picking Packing VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Customer
- Internal Systems

Linked Companies

- Viamed
- VST

Management Review

Viamed - Audits

Trained Staff (3)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)
- Michael Lamb (trained by Helen Lamb)

Associated Documents

- Audit 01 Picking packing Viamed (Doc ID: 173579)
- Audit 01 Picking packing VST (Doc ID: 173583)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #194

Subject: Audit 01 Picking Packing VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 01 due

BEFORE starting Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
384640	Audit 01 Picking Packing VST (194)	01 Jan 2026		Outstanding (133 days)	Derek Lamb
350896	Audit 01 Picking Packing VST (194)	01 Jan 2025	18 Feb 2026	413 days	Derek Lamb

Process ID #7715 — Audit 02 Contract Review Viamed

Last Reviewed: 27 Feb 2026 by Derek Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes

Management Review

Viamed - Audits

Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 02 Contract Review ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 7.2.1
- VIAMED ISO 13485:2008 Manual: 7.2.1.A
- VIAMED ISO 13485:2008 Manual: 7.2.2
- VIAMED ISO 13485:2008 Manual: 7.2.3.A
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.1
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.1.A
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.3.A
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

Management Review

Viamed - Audits

- ISO Auditing Bodies
- Internal Systems
- Customer

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 02 Contract Review and Sales Order Processing Viamed (Doc ID: 163469)
- Audit 02 Contract Review and Sales Order Processing VST (Doc ID: 163467)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #36

Subject: Audit 02 Contract Review Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 02

Review Last years Audit see if its still suitable
Before Proceeding you need to update the Processes attached to the Audit
Search the Document in the Index,
View the Admin Page
Copy and Paste the Attached Processes, replacing them in the current audit

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Any non Conformances from the Audit:
Create a follow up / related Issue,
With a time for Completion
Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

if its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
373964	Audit 02 Contract Review Viamed (36)	01 Sep 2025	27 Feb 2026	179 days	Derek Lamb
339670	Audit 02 Contract Review Viamed (36)	02 Sep 2024	22 Jan 2025	142 days	Helen Lamb

Management Review

Viamed - Audits

Process ID #7763 — Audit 02 Contract Review VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 02 Contract Review VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Customer
- Internal Systems

Management Review

Viamed - Audits

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 02 Contract Review and Sales Order Processing Viamed (Doc ID: 163469)
- Audit 02 Contract Review and Sales Order Processing VST (Doc ID: 163467)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #187

Subject: Audit 02 Contract Review VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 02

Review Last years Audit see if its still suitable
Before Proceeding you need to update the Processes attached to the Audit
Search the Document in the Index,
View the Admin Page
Copy and Paste the Attached Processes, replacing them in the current audit

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Any non Conformances from the Audit:
Create a follow up / related Issue,
With a time for Completion
Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

if its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
373972	Audit 02 Contract Review VST (187)	01 Sep 2025	18 Feb 2026	170 days	Derek Lamb
339678	Audit 02 Contract Review VST (187)	02 Sep 2024	22 Jan 2025	142 days	Helen Lamb

Process ID #7716 — Audit 03 Design Control Viamed

Management Review

Viamed - Audits

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 03 Design Control ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.10
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.7
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.8
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.9
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4

Management Review

Viamed - Audits

- VIAMED ISO 13485:2008 Manual: 7.0
- VIAMED ISO 13485:2008 Manual: 8.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.0
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.2.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 03 Design Control Viamed (Doc ID: 210973)
- Audit 03 Design Control VST (Doc ID: 211516)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #22

Subject: Audit 03 Design Control Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

Audit 03 Design Control

Review Last years Audit see if its still suitable

Before Proceeding you need to update the Processes attached to the Audit

Search the Document in the Index,

View the Admin Page

Copy and Paste the Attached Processes, replacing them in the current audit

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If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Any non Conformances from the Audit:

Create a follow up / related Issue,

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

if its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

Management Review

Viamed - Audits

ID	Subject	Created	Completed	Days to Complete	Investigated By
384633	Audit 03 Design Control Viamed (22)	01 Jan 2026		Outstanding (133 days)	Derek Lamb
350889	Audit 03 Design Control Viamed (22)	01 Jan 2025	27 Feb 2026	422 days	Derek Lamb

Process ID #7764 — Audit 03 Design Control VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 03 Design Control VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
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Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2

Management Review

Viamed - Audits

- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 03 Design Control Viamed (Doc ID: 210973)
- Audit 03 Design Control VST (Doc ID: 211516)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #193

Subject: Audit 03 Design Control VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 03

NOTE DESIGN REMOVED FROM VST, AUDIT NOT REQUIRED.
LEFT IN FOR FUTURE USE

Review Last years Audit see if its still suitable
Before Proceeding you need to update the Processes attached to the Audit
Search the Document in the Index,
View the Admin Page
Copy and Paste the Attached Processes, replacing them in the current audit

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Any non Conformances from the Audit:

Create a follow up / related Issue,

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

if its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

Management Review

Viamed - Audits

ID	Subject	Created	Completed	Days to Complete	Investigated By
384639	Audit 03 Design Control VST (193)	01 Jan 2026		Outstanding (133 days)	Derek Lamb
350895	Audit 03 Design Control VST (193)	01 Jan 2025	18 Feb 2026	413 days	Derek Lamb

Process ID #7885 — Audit 04 Accounts and Finance Viamed

Last Reviewed: 16 Oct 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 23 Oct 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 23 Oct 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 23 Oct 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 23 Oct 2017
Scope / Definition of Process / Objective	Carry out Audit 04 Accounts for Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 23 Oct 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 23 Oct 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal rolling audit issues.	Derek Lamb 23 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- VIAMED ISO 13485:2008 Manual: 8.2.2
- VIAMED ISO 13485:2008 Manual: 8.2.2.A
- VIAMED ISO 13485:2008 Manual: 8.2.2.B
- VIAMED ISO 13485:2008 Manual: 8.2.2.C
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2.1

Management Review

Viamed - Audits

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2.2

Interested Parties

- Internal Systems
- ISO Auditing Bodies

Linked Companies

- Viamed
- VST
- Viamed Properties

Trained Staff (3)

- Derek Lamb (trained by Derek Lamb)
- Helen Lamb (trained by Derek Lamb)
- Steve Nixon (trained by Derek Lamb)

Associated Documents

- Audit 04 Accounts and Finance Viamed (Doc ID: 159427)
- Audit 04 Accounts and Finance VST (Doc ID: 159429)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Task #1055

Subject: Audit 04 Accounts and Finance Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Task To be Completed Carry out Audit 04 Accounts for Both VST and Viamed The Audit itself, Intrastats and physical process being carried out.

Audit 04 Review Last years

Audit see if its still suitable Before Proceeding you need to update the Processes attached to the Audit Search the Document in the Index,

View the Admin Page Copy and Paste the Attached Processes, replacing them in the current audit

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Any non Conformances from the Audit:

Create a follow up / related Issue, With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution if its a major / critical non conformance complete form QC 18

Management Review

Viamed - Audits

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
375127	Audit 04 Accounts and Finance (1055)	11 Sep 2025	24 Oct 2025	43 days	Derek Lamb
340650	Audit 04 Accounts and Finance (1055)	11 Sep 2024	03 Oct 2024	22 days	Derek Lamb

Process ID #8019 — Audit 04 Accounts And Finance VST

Last Reviewed: 27 Feb 2026 by Derek Lamb

Process Maturity (5 of 6 - 83%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	No
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Helen Lamb 14 Sep 2022
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Helen Lamb 14 Sep 2022
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Helen Lamb 14 Sep 2022
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Helen Lamb 14 Sep 2022
Scope / Definition of Process / Objective	Carry out Audit 04 Accounts for VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 14 Sep 2022
Severity of Risk (1-5)	2.Minor	Helen Lamb 14 Sep 2022
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 14 Sep 2022
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 14 Sep 2022
Verification / Effectiveness	This task is verified for effectiveness during internal rolling audit issues.	Helen Lamb 14 Sep 2022
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 14 Sep 2022
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2.2

Management Review

Viamed - Audits

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- Viamed
- VST
- Viamed Properties

Trained Staff (2)

- Helen Lamb (trained by Helen Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 04 Accounts and Finance Viamed (Doc ID: 159427)
- Audit 04 Accounts and Finance VST (Doc ID: 159429)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Task #1196

Subject: Audit 04 Accounts And Finance VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Task To be Completed Carry out Audit 04 Accounts for VST The Audit itself, Intrastats and physical process being carried out.

Audit 04 Review Last years

Audit see if its still suitable Before Proceeding you need to update the Processes attached to the Audit Search the Document in the Index,

View the Admin Page Copy and Paste the Attached Processes, replacing them in the current audit

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Any non Conformances from the Audit:

Create a follow up / related Issue, With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution if its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

Management Review

Viamed - Audits

ID	Subject	Created	Completed	Days to Complete	Investigated By
375129	Audit 04 Accounts And Finance VST (1196)	11 Sep 2025	31 Oct 2025	50 days	Derek Lamb
340651	Audit 04 Accounts And Finance VST (1196)	11 Sep 2024	20 Sep 2024	9 days	Derek Lamb

Process ID #7717 — Audit 05 Purchasing Suppliers Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 05 Purchasing Suppliers Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3

Management Review

Viamed - Audits

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.4.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.4.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 7.4.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.4.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Supplier

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 05 Purchasing suppliers Viamed (Doc ID: 159433)
- Audit 05 Purchasing suppliers VST (Doc ID: 159435)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #37

Subject: Audit 05 Purchasing Suppliers Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 05

BEFORE starting Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Management Review

Viamed - Audits

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
373965	Audit 05 Purchasing Suppliers Viamed (37)	01 Sep 2025	27 Feb 2026	179 days	Derek Lamb
339671	Audit 05 Purchasing Suppliers Viamed (37)	02 Sep 2024	22 Jan 2025	142 days	Derek Lamb

Process ID #7765 — Audit 05 Purchasing Suppliers VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 05 Purchasing Suppliers VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19	Helen Lamb 23 Oct 2020

Management Review

Viamed - Audits

Risk / Benefit Report HSE Implications Calculated Risk Code

or other extreme national or international
circumstance / crisis.

No Action

No health and safety implications

No Action (Frequency=1, Severity=2)

Helen Lamb 28 Jul 2025

Helen Lamb 28 Jul 2025

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Supplier

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 05 Purchasing suppliers Viamed (Doc ID: 159433)
- Audit 05 Purchasing suppliers VST (Doc ID: 159435)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #190

Subject: Audit 05 Purchasing Suppliers VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 05

BEFORE starting Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Management Review

Viamed - Audits

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
373973	Audit 05 Purchasing Suppliers VST (190)	01 Sep 2025	18 Feb 2026	170 days	Derek Lamb
339679	Audit 05 Purchasing Suppliers VST (190)	02 Sep 2024	22 Jan 2025	142 days	Derek Lamb

Process ID #7718 — Audit 06 Calibration Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 06 Calibration Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Derek Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025

Management Review

Viamed - Audits

HSE Implications
Calculated Risk Code

No health and safety implications
No Action (Frequency=1, Severity=2)

Helen Lamb 28 Jul 2025

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 7.5.1.1.D
- VIAMED ISO 13485:2008 Manual: 7.5.1.1.E
- VIAMED ISO 13485:2008 Manual: 7.6
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.5.1.1.D
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.5.1.1.E
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.6
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Physical Sites
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 06 Calibration VIAMED (Doc ID: 186878)
- Audit 06 VST Ltd Calibration (Doc ID: 186880)
- VOP 06 Measurement Control Viamed VST, Calibration, QA Stock (Doc ID: 168580)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #20

Subject: Audit 06 Calibration Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Please Complete Calibration Audit 6

BEFORE starting Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

Management Review

Viamed - Audits

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
364782	Audit 06 Calibration Viamed (20)	20 May 2025	27 Feb 2026	283 days	Derek Lamb
329964	Audit 06 Calibration Viamed (20)	20 May 2024	22 Jan 2025	247 days	Derek Lamb

Process ID #7766 — Audit 06 Calibration VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 06 Calibration VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management	Helen Lamb 26 Oct 2020

Management Review

Viamed - Audits

Covid / Pandemic Notes	review meeting. This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 06 Calibration VIAMED (Doc ID: 186878)
- Audit 06 VST Ltd Calibration (Doc ID: 186880)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #182

Subject: Audit 06 Calibration VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 06

BEFORE starting Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Management Review

Viamed - Audits

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
364785	Audit 06 Calibration VST (182)	20 May 2025	18 Feb 2026	274 days	Derek Lamb
329966	Audit 06 Calibration VST (182)	20 May 2024	22 Jan 2025	247 days	Derek Lamb

Process ID #7719 — Audit 07 Handling And Storage Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit Audit 07 Handling And Storage Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025

Management Review

Viamed - Audits

HSE Implications
Calculated Risk Code

No health and safety implications
No Action (Frequency=1, Severity=2)

Helen Lamb 28 Jul 2025

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.4.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 8.2.2.C
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.2.2.C
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Physical Sites
- Internal Systems
- Supplier

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 07 Handling and Storage Viamed (Doc ID: 184932)
- Audit 07 Handling and Storage VST (Doc ID: 159441)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #25

Subject: Audit 07 Handling And Storage Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 07 handling and stock control

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

Management Review

Viamed - Audits

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
394616	Audit 07 Handling And Storage Viamed (25)	15 Apr 2026		Outstanding (29 days)	Helen Lamb
361544	Audit 07 Handling And Storage Viamed (25)	15 Apr 2025	27 Feb 2026	318 days	Derek Lamb

Process ID #7767 — Audit 07 Handling And Storage VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 07 Handling And Storage VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019

Management Review

Viamed - Audits

Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Physical Sites
- Customer

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 07 Handling and Storage Viamed (Doc ID: 184932)
- Audit 07 Handling and Storage VST (Doc ID: 159441)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #178

Subject: Audit 07 Handling And Storage VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 07

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Management Review

Viamed - Audits

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -
 With a time for Completion
 Immediate Action Plan
 Corrective Action Plan
 Corrective Action
 Confirmation of Resolution
 If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
394617	Audit 07 Handling And Storage VST (178)	15 Apr 2026		Outstanding (29 days)	Helen Lamb
361546	Audit 07 Handling And Storage VST (178)	15 Apr 2025	18 Feb 2026	309 days	Derek Lamb

Process ID #7720 — Audit 08 Training Viamed

Last Reviewed: 27 Feb 2026 by Derek Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 08 Training Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19	Helen Lamb 23 Oct 2020

Management Review

Viamed - Audits

Risk / Benefit Report HSE Implications Calculated Risk Code

or other extreme national or international
circumstance / crisis.

No Action

No health and safety implications

No Action (Frequency=1, Severity=2)

Helen Lamb 28 Jul 2025

Helen Lamb 28 Jul 2025

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Health Safety Manual: 22
- VIAMED ISO 13485:2008 Manual: 4.1.d
- VIAMED ISO 13485:2008 Manual: 4.1.e
- VIAMED ISO 13485:2008 Manual: 5.1.E
- VIAMED ISO 13485:2008 Manual: 6.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 4.1.d
- ISO 9001 Vandagraph Sensor Technologies Manual: 4.1.e
- ISO 9001 Vandagraph Sensor Technologies Manual: 5.1.E
- ISO 9001 Vandagraph Sensor Technologies Manual: 6.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Staff
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 08 Training, Competence and Human Resources Viamed (Doc ID: 162725)
- Audit 08 Training, Competence and Human Resources VST (Doc ID: 162731)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #10

Subject: Audit 08 Training Viamed

Target User: Derek Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 08 Training

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Management Review

Viamed - Audits

Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
368315	Audit 08 Training Viamed (10)	30 Jun 2025	27 Feb 2026	242 days	Derek Lamb
333809	Audit 08 Training Viamed (10)	01 Jul 2024	22 Jan 2025	205 days	Derek Lamb

Process ID #7768 — Audit 08 Training VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 08 Training VST	Derek Lamb 30 Aug 2017
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019

Management Review

Viamed - Audits

Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Staff

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 08 Training, Competence and Human Resources Viamed (Doc ID: 162725)
- Audit 08 Training, Competence and Human Resources VST (Doc ID: 162731)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #184

Subject: Audit 08 Training VST

Target User: Derek Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 08

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Management Review

Viamed - Audits

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
368316	Audit 08 Training VST (184)	30 Jun 2025	18 Feb 2026	233 days	Derek Lamb
333816	Audit 08 Training VST (184)	01 Jul 2024	22 Jan 2025	205 days	Derek Lamb

Process ID #7721 — Audit 09 Goods Inward And Product Identity Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 09 Goods Inward And Product Identity Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025

Management Review

Viamed - Audits

HSE Implications
Calculated Risk Code

No health and safety implications
No Action (Frequency=1, Severity=2)

Helen Lamb 28 Jul 2025

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.4.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.4.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 7.4.3
- VIAMED ISO 13485:2008 Manual: 7.5
- VIAMED ISO 13485:2008 Manual: 7.5.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.4.3
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.5
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.5.5
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Supplier
- Physical Sites

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 09 Goods Inward and Product Identity Viamed (Doc ID: 166168)
- Audit 09 Goods Inward and Product Identity VST (Doc ID: 166164)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #170

Subject: Audit 09 Goods Inward And Product Identity Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 09

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Management Review

Viamed - Audits

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
391100	Audit 09 Goods Inward And Product Identity Viamed (170)	09 Mar 2026		Outstanding (66 days)	Derek Lamb
357925	Audit 09 Goods Inward And Product Identity Viamed (170)	10 Mar 2025	27 Feb 2026	354 days	Derek Lamb

Process ID #7769 — Audit 09 Goods Inward And Product Identity VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 09 Goods Inward And Product Identity VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	review audit and calendar	Helen Lamb 17 Apr 2018

Management Review

Viamed - Audits

Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Physical Sites
- Internal Systems
- Customer

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 09 Goods Inward and Product Identity Viamed (Doc ID: 166168)
- Audit 09 Goods Inward and Product Identity VST (Doc ID: 166164)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #174

Subject: Audit 09 Goods Inward And Product Identity VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 09

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Management Review

Viamed - Audits

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
391101	Audit 09 Goods Inward And Product Identity VST (174)	09 Mar 2026		Outstanding (66 days)	Derek Lamb
357926	Audit 09 Goods Inward And Product Identity VST (174)	10 Mar 2025	18 Feb 2026	345 days	Derek Lamb

Process ID #7722 — Audit 10 Documentation Control Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 10 Documentation Control Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019

Management Review

Viamed - Audits

Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.10
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.8
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 4.2.3
- VIAMED ISO 13485:2008 Manual: 4.2.3.E
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 4.2.3
- ISO 9001 Vandagraph Sensor Technologies Manual: 4.2.3.E
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (3)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)
- Michael Lamb (trained by Helen Lamb)

Associated Documents

- Audit 10 Documentation Control Viamed (Doc ID: 159363)
- Audit 10 Documentation Control VST (Doc ID: 159361)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #27

Subject: Audit 10 Documentation Control Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

BSI Audits Calendar BSI Audit Documentation Control Audit 10.

Management Review

Viamed - Audits

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
366637	Audit 10 Documentation Control Viamed (27)	10 Jun 2025	27 Feb 2026	262 days	Derek Lamb
331854	Audit 10 Documentation Control Viamed (27)	10 Jun 2024	22 Jan 2025	226 days	Derek Lamb

Process ID #7770 — Audit 10 Documentation Control VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 10 Documentation Control VSTAny follow on issues must	Helen Lamb 15 Sep 2025

Management Review

Viamed - Audits

	be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (3)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)
- Michael Lamb (trained by Helen Lamb)

Associated Documents

- Audit 10 Documentation Control Viamed (Doc ID: 159363)
- Audit 10 Documentation Control VST (Doc ID: 159361)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #183

Subject: Audit 10 Documentation Control VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 10

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Management Review

Viamed - Audits

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
366639	Audit 10 Documentation Control VST (183)	10 Jun 2025	18 Feb 2026	253 days	Derek Lamb
331857	Audit 10 Documentation Control VST (183)	10 Jun 2024	22 Jan 2025	226 days	Derek Lamb

Process ID #7723 — Audit 10b Process Verification Viamed

Last Reviewed: 13 Mar 2024 by Michael Lamb

Process Maturity (3 of 6 - 50%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	No
Has Backup Staff	Yes
Reviewed <12 Months	No
Recent Completion Evidence	No

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 10b Process Verification Viamed Now Defunct - See Audit 20	Derek Lamb 13 Mar 2018
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective		
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019

Management Review

Viamed - Audits

Verification / Effectiveness

This task is verified for effectiveness during internal audits and management review meeting. Helen Lamb 26 Oct 2020

Covid / Pandemic Notes

This process is not affected by Covid 19 or other extreme national or international circumstance / crisis. Helen Lamb 23 Oct 2020

Risk / Benefit Report

HSE Implications

Calculated Risk Code

No Action (Frequency=1, Severity=2)

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.4.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.7
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Government E.G. HMRC
- Physical Sites
- Regulations

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 20 Process verification to Management Viamed (Doc ID: 159389)
- Audit 20 Process verification to Management VST (Doc ID: 159391)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Task Completion History (Last 2 Years, Max 20 Items)

No completed tasks in the last 2 years.

Management Review

Viamed - Audits

Process ID #7771 — Audit 10b Process Verification VST

Last Reviewed: 26 Oct 2020 by Helen Lamb

Process Maturity (3 of 6 - 50%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	No
Has Backup Staff	Yes
Reviewed <12 Months	No
Recent Completion Evidence	No

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 10b Process Verification VSTNow Defunct - See Audit 20	Derek Lamb 13 Mar 2018
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective		
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report		
HSE Implications		
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Government E.G. HMRC
- Physical Sites
- Regulations

Linked Companies

- VST
- Viamed

Management Review

Viamed - Audits

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 20 Process verification to Management Viamed (Doc ID: 159389)
- Audit 20 Process verification to Management VST (Doc ID: 159391)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Task Completion History (Last 2 Years, Max 20 Items)

No completed tasks in the last 2 years.

Process ID #7724 — Audit 11 Repairs And Service Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 11 Repairs And Service Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19	Helen Lamb 23 Oct 2020

Management Review

Viamed - Audits

Risk / Benefit Report HSE Implications Calculated Risk Code

or other extreme national or international
circumstance / crisis.

No Action

No health and safety implications

No Action (Frequency=1, Severity=2)

Helen Lamb 28 Jul 2025

Helen Lamb 28 Jul 2025

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 5.1.E
- VIAMED ISO 13485:2008 Manual: 7.5.1.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 5.1.E
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.5.1.2.3 (ISO:13485)
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Customer

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 11 Repairs, Servicing and Returns Viamed (Doc ID: 166158)
- Audit 11 Repairs, Servicing and Returns VST Ltd (Doc ID: 166154)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #171

Subject: Audit 11 Repairs And Service Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 11

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

Management Review

Viamed - Audits

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
368451	Audit 11 Repairs And Service Viamed (171)	01 Jul 2025	27 Feb 2026	241 days	Derek Lamb
333813	Audit 11 Repairs And Service Viamed (171)	01 Jul 2024	22 Jan 2025	205 days	Derek Lamb

Process ID #7772 — Audit 11 Repairs And Service VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 11 Repairs And Service VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management	Helen Lamb 26 Oct 2020

Management Review

Viamed - Audits

Covid / Pandemic Notes	review meeting. This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Customer
- Internal Systems

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 11 Repairs, Servicing and Returns Viamed (Doc ID: 166158)
- Audit 11 Repairs, Servicing and Returns VST Ltd (Doc ID: 166154)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #179

Subject: Audit 11 Repairs And Service VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 11

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Management Review

Viamed - Audits

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
368452	Audit 11 Repairs And Service VST (179)	01 Jul 2025	18 Feb 2026	232 days	Derek Lamb
333815	Audit 11 Repairs And Service VST (179)	01 Jul 2024	22 Jan 2025	205 days	Derek Lamb

Process ID #7725 — Audit 12 CE Files Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 12 CE Files ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025

Management Review

Viamed - Audits

Calculated Risk Code

No Action (Frequency=1, Severity=2)

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 12 CE Files Viamed (Doc ID: 181242)
- Audit 12 CE Files VST (Doc ID: 159451)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #16

Subject: Audit 12 CE Files Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

BSI Audits Calendar BSI Audit CE Files Audit 12

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Management Review

Viamed - Audits

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
392440	Audit 12 CE Files Viamed (16)	23 Mar 2026	07 May 2026	45 days	Derek Lamb
359360	Audit 12 CE Files Viamed (16)	24 Mar 2025	07 Apr 2025	14 days	Derek Lamb

Process ID #7773 — Audit 12 CE Files VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 12 CE Files VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	review date of last audit	Helen Lamb 18 Apr 2018
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Management Review

Viamed - Audits

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 12 CE Files Viamed (Doc ID: 181242)
- Audit 12 CE Files VST (Doc ID: 159451)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #176

Subject: Audit 12 CE Files VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 12

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
392441	Audit 12 CE Files VST (176)	23 Mar 2026		Outstanding (52 days)	Derek Lamb
359361	Audit 12 CE Files VST (176)	24 Mar 2025	18 Feb 2026	331 days	Derek Lamb

Process ID #7726 — Audit 14 Complaints And Corrective Actions Viamed

Management Review

Viamed - Audits

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 14 Complaints And Corrective Actions ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.3.9
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 7.2.3.C
- VIAMED ISO 13485:2008 Manual: 8.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.3.C
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.5.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

Management Review

Viamed - Audits

- ISO Auditing Bodies
- Customer
- MHRA
- Staff
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 14 Complaints and Corrective Actions Viamed (Doc ID: 203281)
- Audit 14 Complaints and Corrective Actions VST (Doc ID: 159453)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #30

Subject: Audit 14 Complaints And Corrective Actions Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

BSI Audits Calendar BSI Audit Customer Complaints Audit 14

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
380837	Audit 14 Complaints And Corrective Actions Viamed (30)	14 Nov 2025	27 Feb 2026	105 days	Derek Lamb
346833	Audit 14 Complaints And Corrective Actions	14 Nov 2024	22 Jan 2025	69 days	Derek Lamb

Management Review

Viamed - Audits

Viamed (30)

Process ID #7774 — Audit 14 Complaints And Corrective Actions VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 14 Complaints And Corrective Actions VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies

Management Review

Viamed - Audits

- Internal Systems
- MHRA
- Customer

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 14 Complaints and Corrective Actions Viamed (Doc ID: 203281)
- Audit 14 Complaints and Corrective Actions VST (Doc ID: 159453)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #189

Subject: Audit 14 Complaints And Corrective Actions VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 14

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
380842	Audit 14 Complaints And Corrective Actions VST (189)	14 Nov 2025	18 Feb 2026	96 days	Derek Lamb
346837	Audit 14 Complaints And Corrective Actions VST (189)	14 Nov 2024	22 Jan 2025	69 days	Derek Lamb

Management Review

Viamed - Audits

Process ID #7727 — Audit 15 Production Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 15 Production ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 7.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.5
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

Management Review

Viamed - Audits

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 15 Production Viamed (Doc ID: 191692)
- Audit 15 Production VST (Doc ID: 159457)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #28

Subject: Audit 15 Production Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 15 Production

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
396118	Audit 15 Production Viamed (28)	01 May 2026		Outstanding (13 days)	Helen Lamb
362949	Audit 15 Production Viamed (28)	01 May 2025	27 Feb 2026	302 days	Derek Lamb

Process ID #7775 — Audit 15 Production VST

Management Review

Viamed - Audits

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 15 Production VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

Management Review

Viamed - Audits

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 15 Production Viamed (Doc ID: 191692)
- Audit 15 Production VST (Doc ID: 159457)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #175

Subject: Audit 15 Production VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 15

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
396124	Audit 15 Production VST (175)	01 May 2026		Outstanding (13 days)	Helen Lamb
362955	Audit 15 Production VST (175)	01 May 2025	18 Feb 2026	293 days	Derek Lamb

Process ID #7959 — Audit 16 Sales And Marketing Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (5 of 6 - 83%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	No
Has Measurable Objective	Yes

Management Review

Viamed - Audits

Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Helen Lamb 26 Oct 2020
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Helen Lamb 26 Oct 2020
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Helen Lamb 26 Oct 2020
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Helen Lamb 26 Oct 2020
Scope / Definition of Process / Objective	Audit to include Sales and Marketing Functions Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Helen Lamb 26 Oct 2020
Severity of Risk (1-5)	1. Negligible	Helen Lamb 26 Oct 2020
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 26 Oct 2020
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 26 Oct 2020
Verification / Effectiveness	We assess the previous issues for any problems or anomalies. Upon final completion of this task any trends, problems or anomalies will be picked up and if needed a separate issue generate so an investigation can be carried out. The final completion of any issue, resulting in a query over the effectiveness, of any task or mini audit, will also be reported on in an issue upon final completion of that task or mini audit.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=1)	

Interested Parties

- ISO Auditing Bodies

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Derek Lamb (trained by Derek Lamb)
- Helen Lamb (trained by Derek Lamb)

Associated Documents

Management Review

Viamed - Audits

- Audit 16 Sales and Marketing Viamed (Doc ID: 159461)
- Audit 16 Sales and Marketing VST (Doc ID: 159463)
- VOP 03 Contract Review, Enquires, Office Processes (Doc ID: 77875)

Rolling Task #1056

Subject: Audit 16 Sales And Marketing Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Task To be Completed Audit to include Sales and Marketing Functions

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
374047	Audit 16 Sales And Marketing Viamed (1056)	01 Sep 2025	09 Oct 2025	38 days	Derek Lamb
339757	Audit 16 Sales And Marketing Viamed (1056)	02 Sep 2024	03 Oct 2024	31 days	Derek Lamb

Process ID #7960 — Audit 16 Sales And Marketing VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (5 of 6 - 83%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	No
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and	Helen Lamb 26 Oct 2020

Management Review

Viamed - Audits

Outputs to the Process	physical process being carried out. All aspects of the Audit have passed review. Or non conformance issues generated.	Helen Lamb 26 Oct 2020
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Helen Lamb 26 Oct 2020
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Helen Lamb 26 Oct 2020
Scope / Definition of Process / Objective	Audit for Sales and MarketingAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 28 Sep 2020
Severity of Risk (1-5)	1.Negligible	Derek Lamb 28 Sep 2020
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 26 Oct 2020
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 26 Oct 2020
Verification / Effectiveness	We assess the previous issues for any problems or anomalies. Upon final completion of this task any trends, problems or anomalies will be picked up and if needed a separate issue generate so an investigation can be carried out. The final completion of any issue, resulting in a query over the effectiveness, of any task or mini audit, will also be reported on in an issue upon final completion of that task or mini audit.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=1)	

Interested Parties

- ISO Auditing Bodies

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Derek Lamb (trained by Helen Lamb)
- Helen Lamb (trained by Helen Lamb)

Associated Documents

- Audit 16 Sales and Marketing Viamed (Doc ID: 159461)
- Audit 16 Sales and Marketing VST (Doc ID: 159463)

Rolling Task #1057

Subject: Audit 16 Sales And Marketing VST

Management Review

Viamed - Audits

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Task To be Completed Audit to include Sales and Marketing Functions

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
374048	Audit 16 Sales And Marketing VST (1057)	01 Sep 2025	09 Oct 2025	38 days	Derek Lamb
339758	Audit 16 Sales And Marketing VST (1057)	02 Sep 2024	03 Oct 2024	31 days	Derek Lamb

Process ID #7728 — Audit 17 Internal Audits Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out	Derek Lamb 30 Aug 2017

Management Review

Viamed - Audits

	and ask questions of the staff performing the task.	
Scope / Definition of Process / Objective	To carry out Audit 17 Internal Audits Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Physical Sites
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 17 Internal Audits Viamed (Doc ID: 159465)
- Audit 17 Internal Audits VST (Doc ID: 159467)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #11

Subject: Audit 17 Internal Audits Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Management Review

Viamed - Audits

Notes:

System Generated

BSI Audits Calendar BSI Audit Internal Audits Audit 17

BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
382120	Audit 17 Internal Audits Viamed (11)	01 Dec 2025	27 Feb 2026	88 days	Derek Lamb
348369	Audit 17 Internal Audits Viamed (11)	02 Dec 2024	22 Jan 2025	51 days	Derek Lamb

Process ID #7776 — Audit 17 Internal Audits VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 17 Internal Audits VSTAny follow on issues must be	Helen Lamb 15 Sep 2025

Management Review

Viamed - Audits

	identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 17 Internal Audits Viamed (Doc ID: 159465)
- Audit 17 Internal Audits VST (Doc ID: 159467)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #191

Subject: Audit 17 Internal Audits VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 17

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Management Review

Viamed - Audits

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
382126	Audit 17 Internal Audits VST (191)	01 Dec 2025	18 Feb 2026	79 days	Derek Lamb
348377	Audit 17 Internal Audits VST (191)	02 Dec 2024	22 Jan 2025	51 days	Derek Lamb

Process ID #7886 — Audit 18 Management Review Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 24 Oct 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 24 Oct 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 24 Oct 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 24 Oct 2017
Scope / Definition of Process / Objective	To carry out Audit 18 Management Review Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 24 Oct 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 24 Oct 2017
Measurable Objective	Check Audit completed. Look at the	Helen Lamb 22 Jul 2019

Management Review

Viamed - Audits

Training Method Required	issue for the completed document. Hands on Learning from experienced staff	Helen Lamb 01 Oct 2019
Verification / Effectiveness	We assess the previous issues for any problems or anomalies. Upon final completion of this task any trends, problems or anomalies will be picked up and if needed a separate issue generate so an investigation can be carried out. The final completion of any issue, resulting in a query over the effectiveness, of any task or mini audit, will also be reported on in an issue upon final completion of that task or mini audit.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Interested Parties

- Internal Systems
- ISO Auditing Bodies

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Derek Lamb (trained by Derek Lamb)
- Helen Lamb (trained by Derek Lamb)

Associated Documents

- Audit 18 Management Review Viamed (Doc ID: 159471)
- Audit 18 Management Review VST (Doc ID: 159473)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #21

Subject: Audit 18 Management Review Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 18

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

Management Review

Viamed - Audits

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
378231	Audit 18 Management Review Viamed (21)	16 Oct 2025	27 Feb 2026	134 days	Derek Lamb
344045	Audit 18 Management Review Viamed (21)	16 Oct 2024	22 Jan 2025	98 days	Derek Lamb

Process ID #7887 — Audit 18 Management Review VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 24 Oct 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 24 Oct 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 24 Oct 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 24 Oct 2017
Scope / Definition of Process / Objective	To carry out Audit 18 Management Review VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 24 Oct 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 24 Oct 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Hands on Learning from experienced	Helen Lamb 01 Oct 2019

Management Review

Viamed - Audits

Verification / Effectiveness	staff We assess the previous issues for any problems or anomalies. Upon final completion of this task any trends, problems or anomalies will be picked up and if needed a separate issue generate so an investigation can be carried out. The final completion of any issue, resulting in a query over the effectiveness, of any task or mini audit, will also be reported on in an issue upon final completion of that task or mini audit.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Derek Lamb (trained by Derek Lamb)
- Helen Lamb (trained by Derek Lamb)

Associated Documents

- Audit 18 Management Review Viamed (Doc ID: 159471)
- Audit 18 Management Review VST (Doc ID: 159473)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #188

Subject: Audit 18 Management Review VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 18

BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Management Review

Viamed - Audits

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -
 With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
378136	Audit 18 Management Review VST (188)	15 Oct 2025	18 Feb 2026	126 days	Derek Lamb
343909	Audit 18 Management Review VST (188)	15 Oct 2024	22 Jan 2025	99 days	Derek Lamb

Process ID #7729 — Audit 19 Health And Saftey Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 19 Health And Safety ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020

Management Review

Viamed - Audits

Covid / Pandemic Notes

This process is not affected by Covid 19 or other extreme national or international circumstance / crisis. Derek Lamb 23 Oct 2020

Risk / Benefit Report

No Action

Helen Lamb 28 Jul 2025

HSE Implications

No health and safety implications

Helen Lamb 28 Jul 2025

Calculated Risk Code

No Action (Frequency=1, Severity=2)

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Health Safety Manual: 04
- VIAMED ISO 13485:2008 Manual: 6.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 6.4
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- Physical Sites
- ISO Auditing Bodies
- Staff
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Viamed (Doc ID: 159483)
- Audit 19 Health and Safety, Working Conditions and Building Fabric Issues VST (Doc ID: 159481)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #13

Subject: Audit 19 Health And Safety Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Do HSE Audit

Audit No 19.

Send out HSE Personnel Questionnaire, and the HSE DSE Personnel Questionnaire and reissue message of the day reminding users all HSE Documents are available in Intrastats

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Management Review

Viamed - Audits

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
371416	Audit 19 Health And Saftey Viamed (13)	01 Aug 2025	27 Feb 2026	210 days	Derek Lamb
336814	Audit 19 Health And Saftey Viamed (13)	01 Aug 2024	22 Jan 2025	174 days	Derek Lamb

Process ID #7777 — Audit 19 Health And Saftey VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 19 Health And Safety VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025

Management Review

Viamed - Audits

Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Staff
- Physical Sites

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Viamed (Doc ID: 159483)
- Audit 19 Health and Safety, Working Conditions and Building Fabric Issues VST (Doc ID: 159481)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #186

Subject: Audit 19 Health And Safety VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Do HSE Audit

Audit No 19

Review Last years Audit see if its still suitable
BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Management Review

Viamed - Audits

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
371423	Audit 19 Health And Saftey VST (186)	01 Aug 2025	18 Feb 2026	201 days	Derek Lamb
336820	Audit 19 Health And Saftey VST (186)	01 Aug 2024	22 Jan 2025	174 days	Derek Lamb

Process ID #7730 — Audit 20 Process Verification To Managment Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 20 Process Verification To Management ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025

Management Review

Viamed - Audits

Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.4.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.5.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.6.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 6.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Filter 90012015: 5
- Filter 90012015: 5.1
- Filter 90012015: 5.1
- VIAMED ISO 13485:2008 Manual: 5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 5.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Government E.G. HMRC
- Physical Sites
- Regulations

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 20 Process verification to Managment Viamed (Doc ID: 159389)
- Audit 20 Process verification to Managment VST (Doc ID: 159391)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 159391)

Management Review

Viamed - Audits

210961)

Rolling Audit #172

Subject: Audit 20 Process Verification To Management Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 20

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
379629	Audit 20 Process Verification To Managment Viamed (172)	03 Nov 2025	27 Feb 2026	116 days	Derek Lamb
345559	Audit 20 Process Verification To Managment Viamed (172)	01 Nov 2024	22 Jan 2025	82 days	Derek Lamb

Process ID #7778 — Audit 20 Process Verification To Managment VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
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Management Review

Viamed - Audits

Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 20 Process Verification To Management VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Government E.G. HMRC
- Physical Sites
- Regulations

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 20 Process verification to Managment Viamed (Doc ID: 159389)
- Audit 20 Process verification to Managment VST (Doc ID: 159391)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 159391)

Management Review

Viamed - Audits

210961)

Rolling Audit #181

Subject: Audit 20 Process Verification To Management VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 20

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
379630	Audit 20 Process Verification To Managment VST (181)	03 Nov 2025	18 Feb 2026	107 days	Derek Lamb
345560	Audit 20 Process Verification To Managment VST (181)	01 Nov 2024	22 Jan 2025	82 days	Derek Lamb

Process ID #7731 — Audit 21 Audit Of Audit Viamed

Last Reviewed: 15 Sep 2025 by Derek Lamb

Process Maturity (5 of 6 - 83%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	No
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
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Management Review

Viamed - Audits

Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 21 Audit Of Audit ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective		
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report		
HSE Implications		
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- VIAMED ISO 13485:2008 Manual: 5.6.2.A
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 5.6.2.A
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 21 Audit of Audit Viamed (Doc ID: 159485)
- Audit 21 Audit of Audit VST (Doc ID: 159487)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 159488)

Management Review

Viamed - Audits

210961)

Rolling Audit #173

Subject: Audit 21 Audit Of Audit Viamed
Target User: Derek Lamb
Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:
System Generated
Audit 21

Review the Audit Calendar Screen
ISO -> Audit Calendar
Complete Audit 21
Confirm if Audit calendar needs changing.

BEFORE starting Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

Any non Conformances from the Audit:
Create a follow up / related Issue,
With a time for Completion
Immediate Action Plan
Corrective Action Plan
Corrective Action
Confirmation of Resolution
If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
382125	Audit 21 Audit Of Audit Viamed (173)	01 Dec 2025	19 Mar 2026	108 days	Derek Lamb
348376	Audit 21 Audit Of Audit Viamed (173)	02 Dec 2024	19 Mar 2026	472 days	Derek Lamb

Process ID #7779 — Audit 21 Audit Of Audit VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Management Review

Viamed - Audits

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 21 Audit Of Audit VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 21 Audit of Audit Viamed (Doc ID: 159485)
- Audit 21 Audit of Audit VST (Doc ID: 159487)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Management Review

Viamed - Audits

Rolling Audit #192

Subject: Audit 21 Audit Of Audit VST

Target User: Derek Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 21 due

Review the Audit Calendar Screen

ISO -> Audit Calendar

Complete Audit 21

Confirm if Audit calendar needs changing.

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
382127	Audit 21 Audit Of Audit VST (192)	01 Dec 2025	18 Feb 2026	79 days	Derek Lamb
348378	Audit 21 Audit Of Audit VST (192)	02 Dec 2024	22 Jan 2025	51 days	Derek Lamb

Process ID #7732 — Audit 22 Post Market Surveillance Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (5 of 6 - 83%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	No
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and	Derek Lamb 26 Oct 2017

Management Review

Viamed - Audits

Outputs to the Process	physical process being carried out. All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 26 Oct 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 26 Oct 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 26 Oct 2017
Scope / Definition of Process / Objective	To carry out Audit 22 Post Market Surveillance ViamedAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 26 Oct 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 26 Oct 2017
Measurable Objective		
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report		
HSE Implications		
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 7.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- Internal Systems
- Customer
- ISO Auditing Bodies
- MHRA

Trained Staff (3)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Derek Lamb)
- Steve Nixon (trained by Derek Lamb)

Associated Documents

- Audit 22 Post Market Surveillance Viamed (Doc ID: 186382)
- Audit 22 Post Market Surveillance VST (Doc ID: 159385)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Management Review

Viamed - Audits

Rolling Audit #14

Subject: Audit 22 Post Market Surveillance Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 22 BSI Audits Calendar BSI Audit Post Marketing Surveillance

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
396003	Audit 22 Post Market Surveillance Viamed (14)	30 Apr 2026		Outstanding (14 days)	Helen Lamb
362859	Audit 22 Post Market Surveillance Viamed (14)	30 Apr 2025	27 Feb 2026	303 days	Helen Lamb

Process ID #7780 — Audit 22 Post Market Surveillance VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017

Management Review

Viamed - Audits

Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	To carry out Audit 22 Post Market Surveillance VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Customer
- MHRA

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 22 Post Market Surveillance Viamed (Doc ID: 186382)
- Audit 22 Post Market Surveillance VST (Doc ID: 159385)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #180

Subject: Audit 22 Post Market Surveillance VST

Target User: Helen Lamb

Management Review

Viamed - Audits

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 22

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

- With a time for Completion
- Immediate Action Plan
- Corrective Action Plan
- Corrective Action
- Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
396004	Audit 22 Post Market Surveillance VST (180)	30 Apr 2026		Outstanding (14 days)	Helen Lamb
362860	Audit 22 Post Market Surveillance VST (180)	30 Apr 2025	18 Feb 2026	294 days	Derek Lamb

Process ID #7733 — Audit 23 Analysis Of Data Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out	Derek Lamb 30 Aug 2017

Management Review

Viamed - Audits

Scope / Definition of Process / Objective	and ask questions of the staff performing the task. To carry out Audit 23 Analysis Of Data Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 4.1.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.4
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 23 Analysis of Data Viamed (Doc ID: 158752)
- Audit 23 Analysis of Data VST (Doc ID: 158748)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #43

Subject: Audit 23 Analysis Of Data Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

Management Review

Viamed - Audits

System Generated
Audit 23

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
369652	Audit 23 Analysis Of Data Viamed (43)	14 Jul 2025	27 Feb 2026	228 days	Derek Lamb
335178	Audit 23 Analysis Of Data Viamed (43)	15 Jul 2024	22 Jan 2025	191 days	Derek Lamb

Process ID #7781 — Audit 23 Analysis Of Data VST

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 30 Aug 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 30 Aug 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 30 Aug 2017
Scope / Definition of Process /	To carry out Audit 23 Analysis Of Data	Helen Lamb 15 Sep 2025

Management Review

Viamed - Audits

Objective	VSTAny follow on issues must be identified with Observation Issue or a Non Conformance Issue.If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Aug 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 30 Aug 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness during internal audits and management review meeting.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- VST
- Viamed

Trained Staff (2)

- Helen Lamb (trained by Derek Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 23 Analysis of Data Viamed (Doc ID: 158752)
- Audit 23 Analysis of Data VST (Doc ID: 158748)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #185

Subject: Audit 23 Analysis Of Data VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated
Audit 23

BEFORE starting the Audit you need to update the Processes attached to the Audit.
Find the doc in the Document Index Admin Document -
Copy and Paste List Processes Per Title replacing them in the current audit.

Management Review

Viamed - Audits

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
369656	Audit 23 Analysis Of Data VST (185)	14 Jul 2025	18 Feb 2026	219 days	Derek Lamb
335184	Audit 23 Analysis Of Data VST (185)	15 Jul 2024	22 Jan 2025	191 days	Derek Lamb

Process ID #7889 — Audit 24 Servicing Viamed

Last Reviewed: 15 Sep 2025 by Helen Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, opera and physical process being carried out.	Derek Lamb 24 Oct 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 24 Oct 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 24 Oct 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 24 Oct 2017
Scope / Definition of Process / Objective	To carry out Audit 24 Servicing Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 24 Oct 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 24 Oct 2017

Management Review

Viamed - Audits

Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 01 Oct 2019
Verification / Effectiveness	We assess the previous issues for any problems or anomalies. Upon final completion of this task any trends, problems or anomalies will be picked up and if needed a separate issue generate so an investigation can be carried out. The final completion of any issue, resulting in a query over the effectiveness, of any task or mini audit, will also be reported on in an issue upon final completion of that task or mini audit.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Interested Parties

- Internal Systems
- ISO Auditing Bodies
- Customer

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Derek Lamb (trained by Derek Lamb)
- Helen Lamb (trained by Derek Lamb)

Associated Documents

- Audit 24 Service Logs Viamed (Doc ID: 159493)
- Audit 24 Service Logs VST (Doc ID: 159491)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Audit #288

Subject: Audit 24 Due Servicing

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Audit 24 Due Servicing

BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Management Review

Viamed - Audits

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
371427	Audit 24 Due Servicing (288)	01 Aug 2025	27 Feb 2026	210 days	Derek Lamb
336824	Audit 24 Due Servicing (288)	01 Aug 2024	22 Jan 2025	174 days	Derek Lamb

Process ID #7892 — Audit 27 Software Validation Viamed

Last Reviewed: 23 Mar 2026 by Derek Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, physical process being carried out.	Derek Lamb 26 Oct 2017
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Derek Lamb 26 Oct 2017
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Derek Lamb 26 Oct 2017
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Derek Lamb 26 Oct 2017
Scope / Definition of Process / Objective	To confirm the Prime functions of the Software used is verified. Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Derek Lamb 26 Oct 2017
Severity of Risk (1-5)	2. Minor	Derek Lamb 26 Oct 2017
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 22 Jul 2019
Training Method Required	Hands on Learning from experienced	Helen Lamb 01 Oct 2019

Management Review

Viamed - Audits

Verification / Effectiveness	staff We assess the previous issues for any problems or anomalies. Upon final completion of this task any trends, problems or anomalies will be picked up and if needed a separate issue generate so an investigation can be carried out. The final completion of any issue, resulting in a query over the effectiveness, of any task or mini audit, will also be reported on in an issue upon final completion of that task or mini audit.	Helen Lamb 26 Oct 2020
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Oct 2020
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Interested Parties

- Internal Systems

Linked Companies

- Viamed

Trained Staff (2)

- Derek Lamb (trained by Derek Lamb)
- Helen Lamb (trained by Derek Lamb)

Associated Documents

- Audit 27 Software Validation Viamed (Doc ID: 156701)
- Audit 27 Software Validation VST (Doc ID: 175712)
- VOP 27 Software Validation (Doc ID: 91486)

Rolling Audit #821

Subject: Audit 27 Software Validation Viamed

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Task To be Completed Audit 27 Software Validation

To confirm the Prime functions of the Software used is verified. The Audit itself, Intrastats, physical process being carried out.

Complete Audit 27

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Management Review

Viamed - Audits

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
388321	Audit 27 Software Validation Viamed (821)	09 Feb 2026		Outstanding (94 days)	Derek Lamb
355055	Audit 27 Software Validation Viamed (821)	10 Feb 2025	23 Mar 2026	405 days	Helen Lamb

Process ID #8079 — Audit 27 Software Validation VST

Last Reviewed: 02 Mar 2026 by Derek Lamb

Process Maturity (6 of 6 - 100%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	Yes
Has Measurable Objective	Yes
Has Backup Staff	Yes
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	The Audit itself, Intrastats, physical process being carried out.	Helen Lamb 10 Jul 2024
Outputs to the Process	All aspects of the Audit have passed review. Or non conformance issues generated.	Helen Lamb 10 Jul 2024
Risks to the Process	That something may impede the Audit, so it cannot be carried out fully.	Helen Lamb 10 Jul 2024
Steps to Minimise Process Risks	Investigate the process being carried out and ask questions of the staff performing the task.	Helen Lamb 10 Jul 2024
Scope / Definition of Process / Objective	To confirm the Prime functions of the Software used is verified. Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1. Improbable	Helen Lamb 10 Jul 2024
Severity of Risk (1-5)	2. Minor	Helen Lamb 10 Jul 2024
Measurable Objective	Check Audit completed. Look at the issue for the completed document.	Helen Lamb 10 Jul 2024

Management Review

Viamed - Audits

Training Method Required	Hands on Learning from experienced staff	Helen Lamb 10 Jul 2024
Verification / Effectiveness	We assess the previous issues for any problems or anomalies. Upon final completion of this task any trends, problems or anomalies will be picked up and if needed a separate issue generate so an investigation can be carried out. The final completion of any issue, resulting in a query over the effectiveness, of any task or mini audit, will also be reported on in an issue upon final completion of that task or mini audit.	Helen Lamb 10 Jul 2024
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 10 Jul 2024
Risk / Benefit Report	No Action	Helen Lamb 28 Jul 2025
HSE Implications	No health and safety implications	Helen Lamb 28 Jul 2025
Calculated Risk Code	No Action (Frequency=1, Severity=2)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2.1

Interested Parties

- Internal Systems

Linked Companies

- VST

Trained Staff (3)

- Helen Lamb (trained by Helen Lamb)
- Michael Lamb (trained by Helen Lamb)
- Derek Lamb (trained by Helen Lamb)

Associated Documents

- Audit 27 Software Validation Viamed (Doc ID: 156701)
- Audit 27 Software Validation VST (Doc ID: 175712)
- VOP 27 Software Validation (Doc ID: 91486)

Rolling Audit #1247

Subject: Audit 27 Software Validation VST

Target User: Helen Lamb

Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

System Generated

Task To be Completed Audit 27 Software Validation

To confirm the Prime functions of the Software used is verified. The Audit itself, Intrastats, physical process being carried out.

BEFORE starting the Audit you need to update the Processes attached to the Audit.

Find the doc in the Document Index Admin Document -

Copy and Paste List Processes Per Title replacing them in the current audit.

Management Review

Viamed - Audits

Review Last years Audit see if its still suitable

Carry out the Audit, reviewing and commenting on the ISO route map first.

Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.

If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.

If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following -

With a time for Completion

Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

If its a major / critical non conformance complete form QC 18

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
388346	Audit 27 Software Validation VST (1247)	09 Feb 2026	27 Apr 2026	77 days	Derek Lamb
355078	Audit 27 Software Validation VST (1247)	10 Feb 2025	27 Mar 2025	45 days	Derek Lamb

Process ID #8115 — Audits Review

Last Reviewed: 14 May 2026 by Derek Lamb

Process Maturity (3 of 6 - 50%)

Measure	Status
Has Risk Assessment	Yes
Has Audit	No
Has Measurable Objective	No
Has Backup Staff	No
Reviewed <12 Months	Yes
Recent Completion Evidence	Yes

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process		
Outputs to the Process		
Risks to the Process		
Steps to Minimise Process Risks		
Scope / Definition of Process / Objective	New Process as of 14 / 05 / 2026.Roles Titles Processes and Procedures ADMIN ViamedEnd column of Audits Review ReviewPrint to PDF,	Derek Lamb 14 May 2026
Likelihood of Risk (1-5)		
Severity of Risk (1-5)		
Measurable Objective		
Training Method Required		
Verification / Effectiveness		
Covid / Pandemic Notes		
Risk / Benefit Report		
HSE Implications		
Calculated Risk Code	NEEDS SETTING (Frequency=0,	

Management Review

Viamed - Audits

Severity=0)

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.5
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.5

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- Viamed

Trained Staff (1)

- Derek Lamb (trained by Derek Lamb)

Associated Documents

- management reviews - Roles Reviews (Doc ID: 220072)

Rolling Task #1335

Subject: Audits Review

Target User: Derek Lamb

Recurrence: 1 Month(s) 0 Week(s) 0 Day(s)

Notes:

System GeneratedTask To be Completed
Roles Titles Processes and Procedures ADMIN Viamed
End column of Audits Review Review
Print to PDF,

Task Completion History (Last 2 Years, Max 20 Items)

ID	Subject	Created	Completed	Days to Complete	Investigated By
397370	Audits Review (1335)	14 May 2026		Outstanding (0 days)	Derek Lamb

Conclusion / Executive Summary

Auto-calculated summary of findings across the report.

Coverage

- 1 roles reviewed
- 50 active processes reviewed

Key Risks

- No critical risks detected.

Overdue Reviews

- 2 process(es) not reviewed in over 24 months

Management Review

Viamed - Audits

Dependency Warnings

- [Audits] Helen Lamb linked to 98% (49 of 50) of role processes - single point of failure risk
- [Audits] Derek Lamb linked to 100% (50 of 50) of role processes - single point of failure risk

Missing Audits

- 4 process(es) with no audit configured (excluding responsibility-only)

Missing Measurable Objectives

- 5 process(es) missing measurable objective

Trained Staff Coverage

- 1 process(es) with only one trained user (no backup)

Process Maturity Overview

- 3 of 50 processes (6%) scored below 4 of 6 maturity checks

Per-Role Risk Indicator Summary

Role	Processes	Overdue	>24mo Review	Solo Trained	No Trained	Missing Obj	No Audit
Audits	50	0	2	1	0	5	4

End of Management Review Report - Viamed