

Management Review

Viamed - ISO and Compliance Controller

Management Review Report

Viamed

Role: ISO and Compliance Controller

Report Date: 14 May 2026

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1. ISO and Compliance Controller (ID #28)
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: ISO and Compliance Controller (ID #28)

Reports To: Managing Director ? Share Holder

Assigned Employees: Derek Lamb, Derek Lamb, Derek Lamb, Derek Lamb

Processes Assigned: 33 (25 active, 8 responsibility-only)

Role Risk Indicators - ISO and Compliance Controller

- **25** linked processes
- **1** overdue rolling tasks/audits
- **1** processes not reviewed >24 months
- **8** processes with only one trained user
- **1** processes missing measurable objective
- **16** processes with no audit configured

Dependency / Single-Point-of-Failure Risk

- Derek Lamb linked to 100% (25 of 25) of role processes - single point of failure risk
- 8 process(es) have only 1 trained employee - no backup coverage

Process ID #7093 — BSI Audits Calander

Last Reviewed: 28 Jul 2025 by Helen Lamb

Process Maturity (5 of 6 - 83%)

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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	Audit Issues	Derek Lamb 26 Sep 2017
Outputs to the Process	Completed Audits	Derek Lamb 26 Sep 2017
Risks to the Process	Audits dont get completed	Derek Lamb 26 Sep 2017
Steps to Minimise Process Risks	rolling Issue 725	Derek Lamb 26 Sep 2017
Scope / Definition of Process / Objective	Review of outstanding Audits	Derek Lamb 26 Sep 2017
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 26 Sep 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 26 Sep 2017
Measurable Objective	Check what audit issues are outstanding and if they are within reasonable terms.	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 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=1)	

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: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.1.1

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 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)

Rolling Task #725

Subject: BSI Audits Calander

Target User: Derek Lamb

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

Notes:

System Generated
Task To be Completed

Check No Top Level Audits are Overdue

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
384683	BSI Audits Calander (725)	01 Jan 2026	09 Apr 2026	98 days	Derek Lamb
350935	BSI Audits Calander (725)	01 Jan 2025	31 Mar 2025	89 days	Derek Lamb

Process ID #7941 — Check Leaflets, Letterhead And Other Paperwork To See If The Correct BSI Logo Is In Use. Remove All Old If Found.

Last Reviewed: 28 Jul 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	leaflets and letter headed paperwebsiteBSi logo	Helen Lamb 23 Sep 2019
Outputs to the Process	correct paperwork available	Helen Lamb 23 Sep 2019
Risks to the Process	that we may miss something and risk BSI non conformance	Helen Lamb 23 Sep 2019
Steps to Minimise Process Risks	Regular review and Issues when needed.	Helen Lamb 23 Sep 2019
Scope / Definition of Process / Objective	Check Leaflets, Letterhead and other paperwork to see if the correct BSI logo is in use. Remove and dispose of all old items if found.Ask Catrin to review the website for old leaflets.	Helen Lamb 23 Sep 2019
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 13 Nov 2021
Severity of Risk (1-5)	3.Serious	Helen Lamb 23 Sep 2019
Measurable Objective	Check and make sure no old stock of paperwork - Leaflets, Letterhead etc is present.	Helen Lamb 23 Sep 2019
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 02 Nov 2021
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

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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=3)	

Interested Parties

- ISO Auditing Bodies

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Derek Lamb (trained by Helen Lamb)
- Helen 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 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records (Doc ID: 120321)

Rolling Task #1005

Subject: Check Leaflets, Letterhead And Other Paperwork To See If The Correct BSI Logo Is In Use. Remove All Old If Found.

Target User: Derek Lamb

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

Notes:

System Generated Task To be Completed

Check we do not have any old leaflets or letterhead. Get Catrin to check website for old leaflets.

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
371479	Check Leaflets, Letterhead And Other Paperwork To See If The Correct BSI Logo Is In Use. Remove All Old If Found. (1005)	01 Aug 2025	05 Aug 2025	4 days	Derek Lamb
336871	Check Leaflets, Letterhead And Other Paperwork To See If The Correct BSI Logo Is In Use. Remove All Old If Found. (1005)	01 Aug 2024	01 Aug 2024	0 days	Derek Lamb

Process ID #5890 — Check Website ISO Documents

Last Reviewed: 10 Sep 2025 by Derek Lamb

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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	Web site	Derek Lamb 22 Aug 2016
Outputs to the Process	confirmation the online documents are our latest versions	Derek Lamb 22 Aug 2016
Risks to the Process	customers download out of date documents.	Derek Lamb 22 Aug 2016
Steps to Minimise Process Risks	rolling Issue to check the online documents	Derek Lamb 22 Aug 2016
Scope / Definition of Process / Objective	Ensure the online available copies of our ISO standards are upto date	Derek Lamb 22 Aug 2016
Likelihood of Risk (1-5)	3.Occasional	Derek Lamb 12 Jun 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 12 Jun 2017
Measurable Objective	Check rolling issues are completed within terms. Also check the web site to the current documentation.	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	not applicable	Derek Lamb 01 Jul 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=3, Severity=1)	

Linked ISO Sections

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

Interested Parties

- ISO Auditing Bodies
- VST OEM Customers
- VST OEM Customers

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Derek Lamb (trained by Derek Lamb)
- Catrin Hird (trained by Derek Lamb)

Associated Documents

- Audit 10 Documentation Control Viamed (Doc ID: 159363)
- Audit 10 Documentation Control VST (Doc ID: 159361)
- VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records (Doc ID: 120321)

Rolling Task #463

Subject: Check Website ISO Documents

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Target User: Catrin Hird

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

Notes:

System Generated

Task To be Completed

Check the documents are still in date and valid

Rolling Audit #464

Subject: Check Website ISO Documents

Target User: Derek Lamb

Recurrence: 6 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

AUDIT Ensure the Task is being Completed

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
396859	Check Website ISO Documents (463)	11 May 2026	14 May 2026	3 days	Catrin Hird
394252	Check Website ISO Documents (463)	10 Apr 2026	16 Apr 2026	6 days	Catrin Hird
391266	Check Website ISO Documents (463)	10 Mar 2026	16 Mar 2026	6 days	Catrin Hird
388419	Check Website ISO Documents (463)	10 Feb 2026	13 Feb 2026	3 days	Catrin Hird
385597	Check Website ISO Documents (463)	12 Jan 2026	19 Jan 2026	7 days	Catrin Hird
384653	Check Website ISO Documents (464)	01 Jan 2026	08 Jan 2026	7 days	Derek Lamb
383039	Check Website ISO Documents (463)	10 Dec 2025	22 Dec 2025	12 days	Catrin Hird
380373	Check Website ISO Documents (463)	10 Nov 2025	20 Nov 2025	10 days	Catrin Hird
377684	Check Website ISO Documents (463)	10 Oct 2025	16 Oct 2025	6 days	Catrin Hird
374977	Check Website ISO Documents (463)	10 Sep 2025	12 Sep 2025	2 days	Catrin Hird
372237	Check Website ISO Documents (463)	11 Aug 2025	12 Sep 2025	32 days	Catrin Hird
369445	Check Website ISO Documents (463)	10 Jul 2025	18 Jul 2025	8 days	Catrin Hird
368461	Check Website ISO Documents (464)	01 Jul 2025	03 Jul 2025	2 days	Derek Lamb
366646	Check Website ISO Documents (463)	10 Jun 2025	19 Jun 2025	9 days	Catrin Hird
363944	Check Website ISO Documents (463)	12 May 2025	15 May 2025	3 days	Catrin Hird
361189	Check Website ISO Documents (463)	10 Apr 2025	14 Apr 2025	4 days	Catrin Hird
357941	Check Website ISO Documents (463)	10 Mar 2025	13 Mar 2025	3 days	Catrin Hird
355023	Check Website ISO Documents (463)	10 Feb 2025	13 Feb 2025	3 days	Derek Lamb
352114	Check Website ISO Documents (463)	10 Jan 2025	17 Jan 2025	7 days	Catrin Hird

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350906	Documents (463) Check Website ISO 01 Jan 2025 Documents (464)	08 Jan 2025	7 days	Derek Lamb
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Process ID #7743 — Customer Complaints Paper File

Last Reviewed: 28 Jul 2025 by Helen Lamb

Process Maturity (4 of 6 - 67%)

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

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	Issues Customer Complaints, and non conformance reviews. See Customer Complaints VM3COP for further details	Derek Lamb 21 Feb 2017
Outputs to the Process	File is kept upto date	Derek Lamb 21 Feb 2017
Risks to the Process	Customer Complaints could be missed or not filed correctly	Helen Lamb 02 Nov 2021
Steps to Minimise Process Risks	Digital system Regular reviews and issues and management meeting	Helen Lamb 02 Nov 2021
Scope / Definition of Process / Objective	Major Customer Complaints get escalated to Paper Customer Complaints file. Check the File is being Maintained and any relevant documentation is in the File.	Derek Lamb 21 Feb 2017
Likelihood of Risk (1-5)	2.Remote	Derek Lamb 12 Jun 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 12 Jun 2017
Measurable Objective	Look at the paper file see when reviewed last.	Helen Lamb 22 Jul 2019
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 02 Nov 2021
Verification / Effectiveness	This task is verified for effectiveness during internal audit and management review.	Helen Lamb 02 Nov 2021
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=2, Severity=1)	

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: 5.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.6.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.6.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.6.2
- 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: 7.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.2.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.3.1

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- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.3.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.5.3
- Filter 90012015: 5.1.2
- VIAMED ISO 13485:2008 Manual: 4.1.a
- VIAMED ISO 13485:2008 Manual: 4.1.b
- VIAMED ISO 13485:2008 Manual: 4.1.c
- VIAMED ISO 13485:2008 Manual: 5.1.A
- VIAMED ISO 13485:2008 Manual: 5.1.A
- VIAMED ISO 13485:2008 Manual: 6.1
- VIAMED ISO 13485:2008 Manual: 7.2.1
- VIAMED ISO 13485:2008 Manual: 7.2.1.A
- VIAMED ISO 13485:2008 Manual: 7.2.1.A
- VIAMED ISO 13485:2008 Manual: 7.2.3
- VIAMED ISO 13485:2008 Manual: 7.2.3.C
- VIAMED ISO 13485:2008 Manual: 7.2.3.C
- VIAMED ISO 13485:2008 Manual: 7.2.3.C
- VIAMED ISO 13485:2008 Manual: 7.2.3.C
- VIAMED ISO 13485:2008 Manual: 7.5.4
- VIAMED ISO 13485:2008 Manual: 8.3
- VIAMED ISO 13485:2008 Manual: 8.3
- VIAMED ISO 13485:2008 Manual: 8.5.1
- VIAMED ISO 13485:2008 Manual: 8.5.1
- VIAMED ISO 13485:2008 Manual: 8.5.2
- VIAMED ISO 13485:2008 Manual: 8.5.3
- 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: 5.1.1
- ISO 9001 Vandagraph Sensor Technologies Manual: 4.1.a
- ISO 9001 Vandagraph Sensor Technologies Manual: 4.1.b
- ISO 9001 Vandagraph Sensor Technologies Manual: 4.1.c
- ISO 9001 Vandagraph Sensor Technologies Manual: 5.1.A
- ISO 9001 Vandagraph Sensor Technologies Manual: 5.1.A
- ISO 9001 Vandagraph Sensor Technologies Manual: 6.1
- 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: 7.2.1.A
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.3
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.3.C
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.3.C
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.3.C
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.2.3.C
- ISO 9001 Vandagraph Sensor Technologies Manual: 7.5.4
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.3
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.3
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.5.1
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.5.1
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.5.2
- ISO 9001 Vandagraph Sensor Technologies Manual: 8.5.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.1.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.3.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Customer
- MHRA
- VST OEM Customers
- VST OEM Customers

Linked Companies

- Viamed

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- VST
- Vandagraph

Trained Staff (1)

- Derek Lamb (trained by Derek Lamb)

Associated Documents

- Audit 14 Complaints and Corrective Actions Viamed (Doc ID: 203281)
- Audit 14 Complaints and Corrective Actions VST (Doc ID: 159453)
- Chart 27 Customer Complaints Chart 27 (Doc ID: 8700)
- QC 11 Customer Complaints Index (Doc ID: 6098)
- QC 12 Customer Complaints Report form QC12 (Doc ID: 6096)
- VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd (Doc ID: 132118)
- VOP 19 Feedback Customer Complaints Vigilance and Notifications VST Ltd (Doc ID: 217154)

Rolling Task #75

Subject: Review Paper Customer Complaints File

Target User: Derek Lamb

Recurrence: 6 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated Review Paper Customer Complaints File

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
392734	Review Paper Customer Complaints File (75)	25 Mar 2026	26 Mar 2026	1 day	Derek Lamb
376214	Review Paper Customer Complaints File (75)	25 Sep 2025	02 Oct 2025	7 days	Derek Lamb
359497	Review Paper Customer Complaints File (75)	25 Mar 2025	25 Mar 2025	0 days	Derek Lamb
341930	Review Paper Customer Complaints File (75)	25 Sep 2024	17 Oct 2024	22 days	Derek Lamb

Process ID #7895 — FDA Device Establishment Registration

Last Reviewed: 28 Jul 2025 by Helen Lamb

Process Maturity (4 of 6 - 67%)

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

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	FDA Website Rolling Issue	Derek Lamb 29 Oct 2017
Outputs to the Process	Continued Registration	Derek Lamb 29 Oct 2017
Risks to the Process	unable to sell in U.S.A	Derek Lamb 29 Oct 2017

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Steps to Minimise Process Risks	rolling task	Derek Lamb 29 Oct 2017
Scope / Definition of Process / Objective	To continue our FDA registration (for the Apgar timer)	Derek Lamb 29 Oct 2017
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 29 Oct 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 29 Oct 2017
Measurable Objective	Check we are listed on the FDA Website,	Derek Lamb 16 Aug 2018
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 generated 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

- Internal Systems
- Regulations
- ISO Auditing Bodies

Linked Companies

- Viamed

Trained Staff (1)

- Derek Lamb (trained by Derek Lamb)

Associated Documents

- Audit 18 Management Review Viamed (Doc ID: 159471)
- Audit 18 Management Review VST (Doc ID: 159473)
- FDA Registration Owner Number (Doc ID: 7026)

Rolling Task #825

Subject: FDA Device Establishment Registration

Target User: Derek Lamb

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

Notes:

System Generated Task To be Completed To Link

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
379689	FDA Device Establishment Registration (825)	03 Nov 2025	06 Nov 2025	3 days	Derek Lamb
345614	FDA Device Establishment Registration (825)	01 Nov 2024	11 Nov 2024	10 days	Derek Lamb

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Process ID #7744 — FDA Device Establishment Registration And Listing

Last Reviewed: 28 Jul 2025 by Helen Lamb

Process Maturity (4 of 6 - 67%)

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

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	Rolling Issue to determine if we wish to renew - based off sales Emails from the FDA with current instructions and Time lines.FDA User Website FDA Product listing WebsiteMDall Website for reviewing current listing	Derek Lamb 21 Feb 2017
Outputs to the Process	Paperwork is generally posted to the FDA, *note paperwork is supplied by the FDA.	Derek Lamb 21 Feb 2017
Risks to the Process	Its harder to initially get on teh register than maintaining it.Inability to sell products in North America	Derek Lamb 21 Feb 2017
Steps to Minimise Process Risks	Rolling Issue	Helen Lamb 22 Jul 2019
Scope / Definition of Process / Objective	FDA registration and the CMDCAS productsIn order to sell in the USA / Canada Markets products need to be registered with the FDA.	Derek Lamb 21 Feb 2017
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 12 Jun 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 12 Jun 2017
Measurable Objective	Check rolling issues are completed within terms.	Helen Lamb 22 Jul 2019
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 02 Nov 2021
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)	

Linked ISO Sections

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.3
- 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: 5.1.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.3

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- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 7.1.5.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 7.1.6
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 7.5.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 7.5.3.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 8.3.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 9.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 4.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 7.1.5.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 7.1.6
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 7.5.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 7.5.3.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 8.3.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.2.1

Interested Parties

- ISO Auditing Bodies
- Internal Systems

Linked Companies

- Viamed

Trained Staff (1)

- Derek Lamb (trained by Derek Lamb)

Associated Documents

- Audit 18 Management Review Viamed (Doc ID: 159471)
- Audit 18 Management Review VST (Doc ID: 159473)
- VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records (Doc ID: 120321)

Rolling Task #565

Subject: FDA Device Establishment Registration And Listing

Target User: Derek Lamb

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

Notes:

System Generated Task To be Completed

Need to decide if we continuing with FDA registration and the CMDCAS products

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
376478	FDA Device Establishment Registration And Listing (565)	29 Sep 2025	02 Oct 2025	3 days	Derek Lamb
342290	FDA Device Establishment Registration And Listing (565)	30 Sep 2024	03 Oct 2024	3 days	Derek Lamb

Process ID #8036 — Future Issues Review

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Viamed - ISO and Compliance Controller

Last Reviewed: 28 Jul 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	Show All Unlinked to Process listprocesses	Helen Lamb 03 Jan 2024
Outputs to the Process	An empty list effective processes that cover all areas of the company	Helen Lamb 03 Jan 2024
Risks to the Process	that we might miss and issue	Helen Lamb 03 Jan 2024
Steps to Minimise Process Risks	regular issues to make sure everything is covered	Helen Lamb 03 Jan 2024
Scope / Definition of Process / Objective	To review any new rolling future issues check they have a processed it is linked to. Make sure it not duplicated	Helen Lamb 03 Jan 2024
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 03 Jan 2024
Severity of Risk (1-5)	1.Negligible	Helen Lamb 03 Jan 2024
Measurable Objective	To review any new rolling future issues Add View Scheduled/Rolling Issues - Show All Unlinked to Process check list is empty	Helen Lamb 03 Jan 2024
Training Method Required	hands on	Helen Lamb 03 Jan 2024
Verification / Effectiveness	This task is verified for effectiveness during internal rolling audit issues.	Helen Lamb 03 Jan 2024
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 03 Jan 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=1)	

Interested Parties

- ISO Auditing Bodies

Linked Companies

- Vandagraph
- Viamed
- Viamed Properties
- 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 Task #1234

Management Review

Viamed - ISO and Compliance Controller

Subject: Future Issues Review

Target User: Derek Lamb

Recurrence: 6 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated Task To be Completed To review any new rolling future issues

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
384086	Future Issues Review (1234)	22 Dec 2025	29 Dec 2025	7 days	Derek Lamb
367656	Future Issues Review (1234)	20 Jun 2025	26 Jun 2025	6 days	Derek Lamb
350308	Future Issues Review (1234)	20 Dec 2024	27 Dec 2024	7 days	Derek Lamb
332955	Future Issues Review (1234)	20 Jun 2024	04 Jul 2024	14 days	Derek Lamb

Process ID #7833 — Importance Of Effective Quality Management

Last Reviewed: 02 Apr 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	Reminder Issue	Derek Lamb 20 Sep 2017
Outputs to the Process	Read only Issue sent to All current Employees so they acknowledge the importance of the Quality Management System	Derek Lamb 20 Sep 2017
Risks to the Process	people may become careless	Helen Lamb 22 Jul 2019
Steps to Minimise Process Risks	Keep up to date with issues.	Helen Lamb 22 Jul 2019
Scope / Definition of Process / Objective	To Remind Staff of the Importance of the ISO systems and they should be following the procedures	Derek Lamb 20 Sep 2017
Likelihood of Risk (1-5)	2.Remote	Derek Lamb 20 Sep 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 20 Sep 2017
Measurable Objective	Check rolling issues are completed within terms. Check issues.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	Helen Lamb 01 Oct 2019
Verification / Effectiveness	regular reviews and issues	Helen Lamb 28 Jul 2025
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=2, Severity=1)	
Linked ISO Sections		

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Viamed - ISO and Compliance Controller

- 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: 5.3
- 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 ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.1.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.2.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.2.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.1.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.3.2

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)
- VM3COP00.00 VOP00.00 Viamed Quality Statement policy and objectives (Doc ID: 164833)
- VM3COP00.00 VOP00.00 VST Quality Statement policy and objectives (Doc ID: 164813)
- VOP 12 Training (Doc ID: 166222)

Rolling Task #732

Subject: Importance Of Effective Quality Management ISO

Target User: Derek Lamb

Recurrence: 6 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Task To be Completed

Post Read Only Issue to all Staff

Reminder to All staff

VST is ISO 9001:2015 Registered.

Viamed is ISO 13485:2016 Registered.

Its important you follow procedures and raise non conformances if things go wrong.

Please re-read VM3COP00.00

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
393306	Importance Of Effective Quality	01 Apr 2026	09 Apr 2026	8 days	Derek Lamb

Management Review

Viamed - ISO and Compliance Controller

Issue ID	Issue Description	Start Date	End Date	Duration	Owner
376738	Management ISO (732) Importance Of Effective Quality Management ISO (732)	01 Oct 2025	09 Oct 2025	8 days	Derek Lamb
360188	Management ISO (732) Importance Of Effective Quality Management ISO (732)	01 Apr 2025	15 May 2025	44 days	Derek Lamb
342445	Management ISO (732) Importance Of Effective Quality Management ISO (732)	01 Oct 2024	10 Oct 2024	9 days	Derek Lamb

Process ID #6866 — Internal Process Verification Complete Systems Review

Last Reviewed: 03 Nov 2021 by Derek Lamb

Process Maturity (2 of 6 - 33%)

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

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	review of all the system processes	Derek Lamb 26 Sep 2017
Outputs to the Process	Confirm the system is suitable for purpose	Derek Lamb 26 Sep 2017
Risks to the Process	Review not carried out	Helen Lamb 02 Nov 2021
Steps to Minimise Process Risks	Keep up to date with issues.	Helen Lamb 22 Jul 2019
Scope / Definition of Process / Objective	Review the Internal Process and Verification`s are suitable for the current standards PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20	Derek Lamb 03 Nov 2021
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 26 Sep 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 26 Sep 2017
Measurable Objective	Check rolling issues are completed within terms.	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 HSE Implications

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Viamed - ISO and Compliance Controller

Calculated Risk Code **No Action** (Frequency=1, Severity=1)

Linked ISO Sections

- 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: 8.5.3
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 4.4.1

Interested Parties

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

Linked Companies

- Viamed
- VST

Trained Staff (1)

- Derek Lamb (trained by Derek Lamb)

Associated Documents

- Audit 20 Process verification to Managment Viamed (Doc ID: 159389)
- Audit 20 Process verification to Managment VST (Doc ID: 159391)
- Internal process verification (Doc ID: 8948)
- 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 #8107 — ISO And Compliance Controller 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 ISO And Compliance Controller Responsibilitys	Derek Lamb 14 May 2026

Management Review

Viamed - ISO and Compliance Controller

ReviewPrint to PDF,

- 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, 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 #1328

Subject: ISO And Compliance Controller 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 ISO And Compliance Controller Responsibilitys Review
Print to PDF,

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
397363	ISO And Compliance Controller Review (1328)	14 May 2026		Outstanding (0 days)	Derek Lamb

Process ID #6871 — ISO14001 Environmental management systems

Last Reviewed: 28 Jul 2025 by Helen Lamb

Process Maturity (4 of 6 - 67%)

Measure	Status

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Viamed - ISO and Compliance Controller

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

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	If we went for this, we would have the standard and its documentation	Helen Lamb 02 Nov 2021
Outputs to the Process	If we went for this, we would have a effective Environmental management systems	Helen Lamb 02 Nov 2021
Risks to the Process	If we went for this, the risks would be incomplete data or ineffective system	Helen Lamb 02 Nov 2021
Steps to Minimise Process Risks	If we went for this, we would carry out regular review and meetings	Helen Lamb 02 Nov 2021
Scope / Definition of Process / Objective	Not yet Applied Rolling Issue to see if we should apply this standard in the future	Derek Lamb 26 Sep 2017
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 26 Sep 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 26 Sep 2017
Measurable Objective	If we went for this, we would have documentation to measure our processes against	Helen Lamb 02 Nov 2021
Training Method Required	If we went for this it would be Hands on Learning from experienced staff	Helen Lamb 02 Nov 2021
Verification / Effectiveness	If we went for this we would 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 02 Nov 2021
Covid / Pandemic Notes	If we went for this. This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 02 Nov 2021
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)	

Linked ISO Sections

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

Interested Parties

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

Linked Companies

- Viamed
- VST

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Trained Staff (1)

- Derek 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 Task #748

Subject: ISO14001 Environmental management systems

Target User: Derek Lamb

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

Notes:

System Generated

Task To be Completed

Review if we should be trying to go for this standard

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
376379	ISO14001 Environmental management systems (748)	26 Sep 2025	02 Oct 2025	6 days	Helen Lamb
342081	ISO14001 Environmental management systems (748)	26 Sep 2024	03 Oct 2024	7 days	Helen Lamb

Process ID #7199 — Non Conformities Review Viamed

Last Reviewed: 19 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	Non Conformance Issue History	Derek Lamb 20 Sep 2017
Outputs to the Process	To Fix / Stop a non conformance reoccurring	Derek Lamb 20 Sep 2017
Risks to the Process	Non conformances go unfixed	Derek Lamb 07 Oct 2021
Steps to Minimise Process Risks	Reports to highlight Nonconformances	Derek Lamb 07 Oct 2021
Scope / Definition of Process / Objective	To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement.	Derek Lamb 20 Sep 2017
Likelihood of Risk (1-5)	2.Remote	Derek Lamb 12 Nov 2021

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Severity of Risk (1-5)	2.Minor	Derek Lamb 12 Nov 2021
Measurable Objective	look at the past non conformance review and make sure it has been issued within three months	Helen Lamb 29 Aug 2018
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=2, Severity=2)	

Linked ISO Sections

- 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: 4.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 8.5.3
- 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: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.1.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.3.2

Interested Parties

- Internal Systems
- MHRA
- ISO Auditing Bodies

Linked Companies

- Viamed

Trained Staff (2)

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

Associated Documents

- Audit 14 Complaints and Corrective Actions Viamed (Doc ID: 203281)
- Audit 14 Complaints and Corrective Actions VST (Doc ID: 159453)
- VM3COP27.46 Non Conformance review (How Too) (Doc ID: 70247)
- VM3COP27.46 Non Conformance review (How Too) (Doc ID: 76237)
- VOP 10 Non Conformance, Corrective and Preventive Actions (Doc ID: 215244)

Rolling Task #283

Subject: Non conformance review history Viamed

Target User: Helen Lamb

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

Notes:

System Generated

Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring.

Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report.

Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to

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see if anything internal / staff / process related needs to be highlighted.

Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted.

Note any problems in the issue and send to Derek to review

Rolling Audit #284

Subject: Non conformance review history Viamed

Target User: Derek Lamb

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

Notes:

System Generated

Check the below review is being carried out

Check the history of the last Non conformance review,

check actions are being carried out,

and non conformances are not reoccurring

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
396370	Non conformance review history Viamed (283)	05 May 2026	14 May 2026	9 days	Derek Lamb
393572	Non conformance review history Viamed (283)	06 Apr 2026	22 Apr 2026	16 days	Derek Lamb
390871	Non conformance review history Viamed (283)	05 Mar 2026	22 Apr 2026	48 days	Derek Lamb
387858	Non conformance review history Viamed (283)	05 Feb 2026	22 Apr 2026	76 days	Helen Lamb
387730	Non conformance review history Viamed (284)	04 Feb 2026	10 Feb 2026	6 days	Derek Lamb
384914	Non conformance review history Viamed (283)	05 Jan 2026	22 Apr 2026	107 days	Derek Lamb
382670	Non conformance review history Viamed (283)	05 Dec 2025	22 Apr 2026	138 days	Derek Lamb
380043	Non conformance review history Viamed (283)	05 Nov 2025	22 Apr 2026	168 days	Derek Lamb
377121	Non conformance review history Viamed (283)	06 Oct 2025	22 Apr 2026	198 days	Derek Lamb
374604	Non conformance review history Viamed (283)	05 Sep 2025	22 Apr 2026	229 days	Helen Lamb
371760	Non conformance review history Viamed (283)	05 Aug 2025	22 Apr 2026	260 days	Derek Lamb

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369024	Non conformance review history Viamed (283)	07 Jul 2025	22 Apr 2026	289 days	Derek Lamb
366217	Non conformance review history Viamed (283)	05 Jun 2025	22 Apr 2026	321 days	Derek Lamb
363193	Non conformance review history Viamed (283)	05 May 2025	22 Apr 2026	352 days	Derek Lamb
360739	Non conformance review history Viamed (283)	07 Apr 2025	22 Apr 2026	380 days	Helen Lamb
357468	Non conformance review history Viamed (283)	05 Mar 2025	22 Apr 2026	413 days	Derek Lamb
354618	Non conformance review history Viamed (283)	05 Feb 2025	22 Apr 2026	441 days	Helen Lamb
354495	Non conformance review history Viamed (284)	04 Feb 2025	13 Feb 2025	9 days	Derek Lamb
351232	Non conformance review history Viamed (283)	06 Jan 2025	22 Apr 2026	471 days	Derek Lamb
348822	Non conformance review history Viamed (283)	05 Dec 2024	22 Apr 2026	503 days	Derek Lamb

Process ID #7071 — Post Market Surveillance

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	Intrastats and current regulations.	Derek Lamb 30 Aug 2017
Outputs to the Process	Notified body notification Updated post market surveillance on products. updates risk assessments.	Derek Lamb 30 Aug 2017
Risks to the Process	Loss of certifications Unforeseen product risks.	Derek Lamb 30 Aug 2017
Steps to Minimise Process Risks	Rolling tasks and Issue. This process is audited.	Derek Lamb 30 Aug 2017
Scope / Definition of Process / Objective	The process by which re view and risk assess all product files, check that no Products / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.	Helen Lamb 15 Sep 2025
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 13 Nov 2021
Severity of Risk (1-5)	3.Serious	Derek Lamb 12 Nov 2021

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Measurable Objective	Check Audit completed. Look at the issue Helen Lamb 22 Jul 2019 for the completed document.
Training Method Required	Hands on Learning from experienced staff Helen Lamb 01 Oct 2019
Verification / Effectiveness	This task is verified for effectiveness Derek Lamb 23 Oct 2020 during internal rolling audit issues.
Covid / Pandemic Notes	This process is not affected by Covid 19 Helen Lamb 23 Oct 2020 or other extreme national or international circumstance / crisis.
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=3)

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 VST Ltd ISO9001:2015+A1: 9.1.3

Interested Parties

- Internal Systems
- Customer
- ISO Auditing Bodies
- MHRA
- VST OEM Customers
- VST OEM Customers
- VST Supplier
- VST Supplier

Linked Companies

- Generic
- Viamed
- VST

Trained Staff (2)

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

Associated Documents

- Audit 12 CE Files Viamed (Doc ID: 181242)
- Audit 12 CE Files VST (Doc ID: 159451)
- 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 Task #50

Subject: Product / Design Changes, are any Post Market Surveillance reviews due

Target User: Derek Lamb

Recurrence: 2 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Check that no Products / Designs have changed significantly to warrant informing MDR / Bsi or any other related Body.

First Check the Stockbox -> QA Fails Review (Slow Page) in case there are any products that have a New repair code that requires a risk assesment

Reprint the Risk Assessment Questions update the file in the index

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Viamed - ISO and Compliance Controller

Carry out the Technical File PMS Post Market Surveillance. Form for Each OBL and Viamed Product
Rename the file to include Periodic Safety Update Report in the title

Using procedure VM3COP27.11
then VM3COP18
for each product range required

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
393408	Product / Design Changes, are any Post Market Surveillance reviews due (50)	02 Apr 2026	09 Apr 2026	7 days	Derek Lamb
387420	Product / Design Changes, are any Post Market Surveillance reviews due (50)	02 Feb 2026	05 Feb 2026	3 days	Derek Lamb
382316	Product / Design Changes, are any Post Market Surveillance reviews due (50)	02 Dec 2025	04 Dec 2025	2 days	Derek Lamb
376811	Product / Design Changes, are any Post Market Surveillance reviews	02 Oct 2025	02 Oct 2025	0 days	Derek Lamb

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371605	due (50) Product / Design Changes, are any Post Market Surveillance reviews	04 Aug 2025	05 Aug 2025	1 day	Derek Lamb
365768	due (50) Product / Design Changes, are any Post Market Surveillance reviews	02 Jun 2025	05 Jun 2025	3 days	Derek Lamb
362859	due (50) Audit 22 Post Market Survellance Viamed (14)	30 Apr 2025	27 Feb 2026	303 days	Helen Lamb
360316	Product / Design Changes, are any Post Market Surveillance reviews	02 Apr 2025	07 Apr 2025	5 days	Derek Lamb
354298	due (50) Product / Design Changes, are any Post Market Surveillance reviews	03 Feb 2025	06 Feb 2025	3 days	Derek Lamb
348370	due (50) Product / Design Changes, are any Post Market Surveillance reviews	02 Dec 2024	04 Dec 2024	2 days	Derek Lamb
342569	due (50) Product / Design Changes, are any Post Market Surveillance reviews	02 Oct 2024	10 Oct 2024	8 days	Derek Lamb
336946	due (50) Product / Design Changes, are any Post Market Surveillance reviews	02 Aug 2024	05 Aug 2024	3 days	Derek Lamb
331176	due (50) Product / Design Changes, are any Post Market Surveillance reviews	03 Jun 2024	06 Jun 2024	3 days	Derek Lamb

Process ID #7978 — Regulatory Requirements and Review of QC21 form template

Last Reviewed: 28 Jul 2025 by Helen Lamb

Process Maturity (4 of 6 - 67%)

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

Risk Assessment

Management Review

Viamed - ISO and Compliance Controller

Risk Item	Notes / Value	Last Updated
Input to the Process	Regulatory bodiesInternal documentationQC 21 form	Helen Lamb 15 Aug 2022
Outputs to the Process	Up to date documentation	Helen Lamb 11 Nov 2021
Risks to the Process	That we will miss updates	Helen Lamb 11 Nov 2021
Steps to Minimise Process Risks	Regular review and issues	Helen Lamb 11 Nov 2021
Scope / Definition of Process / Objective	To Regulatory Requirements and a Review of QC21 form template. To ensure they are up to date to the current standardsreview Qc 21 Form to ensure it is still appropriate and valid	Helen Lamb 15 Aug 2022
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 11 Nov 2021
Severity of Risk (1-5)	3.Serious	Helen Lamb 11 Nov 2021
Measurable Objective	That the issue has been carried out and the documentation has been reviewed annually.	Helen Lamb 11 Nov 2021
Training Method Required	Hands on by with experience staff	Helen Lamb 11 Nov 2021
Verification / Effectiveness	This task is verified for effectiveness during external audits and BSI visits.	Helen Lamb 15 Nov 2021
Covid / Pandemic Notes	Not affected by Covid 19 or other national or international crisis	Helen Lamb 15 Aug 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=3)	

Interested Parties

- Regulations
- Internal Systems

Linked Companies

- Viamed
- VST

Trained Staff (1)

- Derek Lamb (trained by Helen 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 Task #48

Subject: Regulatory Requirements

Target User: Derek Lamb

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

Notes:

System Generated

Ensure all Regulatory requirements are up to date, Check those that relate to the MDR for our discontinued products that are still with in their lifespans.

Check the QC21 form template is still ok to use and doesn't need any updates

Complete the Document up to date reviews on all documents.

European Commission harmonised standards to check documentation upto date

Management Review

Viamed - ISO and Compliance Controller

http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
379031	Regulatory Requirements (48)	27 Oct 2025	30 Oct 2025	3 days	Derek Lamb
345055	Regulatory Requirements (48)	28 Oct 2024	21 Nov 2024	24 days	Derek Lamb

Process ID #8089 — Review Any Outstanding QC 21 Forms To Sign Off

Last Reviewed: 28 Jul 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	QC 21 formsIssues	Helen Lamb 07 Feb 2025
Outputs to the Process	QC 21 forms underway and completed	Helen Lamb 07 Feb 2025
Risks to the Process	Forms started might be missed, left uncompleted	Helen Lamb 07 Feb 2025
Steps to Minimise Process Risks	regular reviews of all open QC21 forms and their issues.	Helen Lamb 07 Feb 2025
Scope / Definition of Process / Objective	Review Any Outstanding QC 21 Forms. If completed, sign it off. Review it to make sure all parts are completed satisfactorily	Helen Lamb 07 Feb 2025
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 07 Feb 2025
Severity of Risk (1-5)	3.Serious	Helen Lamb 07 Feb 2025
Measurable Objective	QC 21 forms underway and completed. Make sure completed or being worked on.	Helen Lamb 07 Feb 2025
Training Method Required	Hands on by experienced members of staff	Helen Lamb 07 Feb 2025
Verification / Effectiveness	regular reviews of the QC21 forms and the rolling issue.	Helen Lamb 07 Feb 2025
Covid / Pandemic Notes	This is not affected by any national or international emergency or pandemic.	Helen Lamb 07 Feb 2025
Risk / Benefit Report	There is a risk of an uncompleted form being missed. This process is here to reduce the likelihood of this ever happening.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=3)	
Linked ISO Sections		

- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO13485:2016: 5.6.2

Management Review

Viamed - ISO and Compliance Controller

- 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 VST Ltd ISO9001:2015+A1: 8.7.1

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

Rolling Task #1276

Subject: Review Any Outstanding QC 21 Forms To Sign Off

Target User: Derek Lamb

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

Notes:

System Generated
Task To be Completed

Review Any Outstanding QC 21 Forms

Rolling Audit #1277

Subject: Review Any Outstanding QC 21 Forms To Sign Off

Target User: Helen Lamb

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

Notes:

System Generated Task To be Completed

This is an audit to check the task is being completed.

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
396693	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 May 2026	Completed	Outstanding (7 days)	Derek Lamb
393703	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 Apr 2026	16 Apr 2026	9 days	Derek Lamb
391167	Review Any Outstanding QC 21 Forms To Sign Off	09 Mar 2026	19 Mar 2026	10 days	Derek Lamb

Management Review

Viamed - ISO and Compliance Controller

388347	(1276) Review Any Outstanding QC 21 Forms To Sign Off	09 Feb 2026	10 Feb 2026	1 day	Derek Lamb
385242	(1276) Review Any Outstanding QC 21 Forms To Sign Off	07 Jan 2026	19 Jan 2026	12 days	Derek Lamb
382860	(1276) Review Any Outstanding QC 21 Forms To Sign Off	08 Dec 2025	22 Dec 2025	14 days	Derek Lamb
380303	(1276) Review Any Outstanding QC 21 Forms To Sign Off	07 Nov 2025	20 Nov 2025	13 days	Derek Lamb
378839	QC 21 Non Conformance Report - We have labelled 25 Maxtec MAX55E 0110452 sensors as MAX250E 01104294, in goods in.	22 Oct 2025	12 Jan 2026	82 days	Derek Lamb
377333	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 Oct 2025	09 Oct 2025	2 days	Derek Lamb
375175	BSI Non Conformance 2700663-202509-N2	11 Sep 2025		Outstanding (245 days)	Helen Lamb
375173	BSI Non Conformance 2700663-202509-N1	11 Sep 2025		Outstanding (245 days)	Helen Lamb
374782	Review Any Outstanding QC 21 Forms To Sign Off (1276)	08 Sep 2025	12 Sep 2025	4 days	Derek Lamb
372047	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 Aug 2025	07 Aug 2025	0 days	Derek Lamb
369096	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 Jul 2025	10 Jul 2025	3 days	Derek Lamb
367537	Review Any Outstanding QC 21 Forms To Sign Off (1277)	19 Jun 2025	26 Jun 2025	7 days	Helen Lamb
366523	Review Any Outstanding QC 21 Forms To Sign Off (1276)	09 Jun 2025	12 Jun 2025	3 days	Derek Lamb
363452	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 May 2025	08 May 2025	1 day	Derek Lamb
360814	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 Apr 2025	02 May 2025	25 days	Derek Lamb

Management Review

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357818	Review Any Outstanding QC 21 Forms To Sign Off (1276)	07 Mar 2025	07 Mar 2025	0 days	Derek Lamb
355079	Review Any Outstanding QC 21 Forms To Sign Off (1276)	10 Feb 2025	13 Feb 2025	3 days	Derek Lamb

Process ID #7980 — Review Gov Website For Applicable Required Standards ISO9001

Last Reviewed: 17 Nov 2025 by Derek Lamb

Process Maturity (4 of 6 - 67%)

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

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	ISO 9001 standard reviews	Helen Lamb 15 Nov 2021
Outputs to the Process	up to date ISO 9001 standard	Helen Lamb 15 Nov 2021
Risks to the Process	A regulatory update could be missed, so we are not assessing to the correct version of the standard	Helen Lamb 15 Nov 2021
Steps to Minimise Process Risks	regular task reviews so these are keep up to date	Helen Lamb 15 Nov 2021
Scope / Definition of Process / Objective	Review the Government Website For Applicable Required Standards ISO 9001 Check if any other standards have been introduced that may have an affect on the company www.gov.uk European Commission harmonised standards to check documentation upto date http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm	Derek Lamb 15 Nov 2021
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 15 Nov 2021
Severity of Risk (1-5)	2.Minor	Helen Lamb 15 Nov 2021
Measurable Objective	Check the issue has been done and the review date	Helen Lamb 15 Nov 2021
Training Method Required	Hands on by experianced member of staff	Derek Lamb 15 Nov 2021
Verification / Effectiveness	This task is verified for effectiveness during external audits and BSI visits.	Helen Lamb 15 Nov 2021
Covid / Pandemic Notes	this is not affected by Covid 19 or other national or international crisis	Helen Lamb 15 Nov 2021
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
- Government E.G. HMRC

Management Review

Viamed - ISO and Compliance Controller

Linked Companies

- VST

Trained Staff (1)

- Derek Lamb (trained by Helen 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 Task #1103

Subject: Review Gov Website For Applicable Required Standards ISO9001

Target User: Derek Lamb

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

Notes:

System GeneratedTask To be Completed

Process needs updating and completing

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
381016	Review Gov Website For Applicable Required Standards ISO9001 (1103)	17 Nov 2025	20 Nov 2025	3 days	Derek Lamb
347193	Review Gov Website For Applicable Required Standards ISO9001 (1103)	18 Nov 2024	21 Nov 2024	3 days	Derek Lamb

Process ID #5887 — Review ISO/EN Documents

Last Reviewed: 28 Jul 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	Uninformed Standards Web Site IntraStats Document index. Technical Files	Derek Lamb 12 Jun 2017
Outputs to the Process	Update of Required standards, Updated Technical Files	Derek Lamb 12 Jun 2017
Risks to the Process	Shipping products and or services with below regulations and or standards	Derek Lamb 12 Jun 2017

Management Review

Viamed - ISO and Compliance Controller

Steps to Minimise Process Risks	Rolling IssueReview on Stanards / LegislationRegular review of Technical file sections to research each affected standards when updated	Derek Lamb 12 Jun 2017
Scope / Definition of Process / Objective	To Keep Products and Services up-to date with current regulations and standards	Derek Lamb 12 Jun 2017
Likelihood of Risk (1-5)	2.Remote	Derek Lamb 12 Jun 2017
Severity of Risk (1-5)	2.Minor	Derek Lamb 12 Jun 2017
Measurable Objective	Check rolling issues are completed within terms.	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 external BSI 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=2, Severity=2)	

Linked ISO Sections

- 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 ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.3.2

Interested Parties

- ISO Auditing Bodies
- Internal Systems
- Regulations

Linked Companies

- Viamed
- VST

Trained Staff (2)

- Derek Lamb (trained by Derek Lamb)
- John Lamb (trained by Derek Lamb)

Associated Documents

- Audit 03 Design Control Viamed (Doc ID: 210973)
- Audit 03 Design Control VST (Doc ID: 211516)
- Viamed Certification ISO 13485:2016 MD78787 (Doc ID: 176874)
- Viamed ISO 13485:2016 Scope (Doc ID: 168096)
- VM3COP02.01 Exclusions to Viamed ISO13485:2016 boundaries of ISO (Doc ID: 74571)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)
- VST - ISO 9001:2015 Certificate FM 607767 (Doc ID: 218795)
- VST ISO 9001:2015 Scope (Doc ID: 164901)

Rolling Task #235

Subject: Review ISO documents

Target User: Derek Lamb

Recurrence: 3 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated

Management Review

Viamed - ISO and Compliance Controller

ISO -> Document up-to date reviews

Review list.

Ensure any out of date documents as renamed as out of date.

If required purchase new version and review changes.

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
392613	Review ISO documents (235)	24 Mar 2026	02 Apr 2026	9 days	Derek Lamb
384218	Review ISO documents (235)	24 Dec 2025	02 Jan 2026	9 days	Derek Lamb
376083	Review ISO documents (235)	24 Sep 2025	25 Sep 2025	1 day	Derek Lamb
367884	Review ISO documents (235)	24 Jun 2025	03 Jul 2025	9 days	Derek Lamb
359363	Review ISO documents (235)	24 Mar 2025	25 Mar 2025	1 day	Derek Lamb
350509	Review ISO documents (235)	24 Dec 2024	27 Dec 2024	3 days	Derek Lamb
341793	Review ISO documents (235)	24 Sep 2024	17 Oct 2024	23 days	Derek Lamb
333168	Review ISO documents (235)	24 Jun 2024	04 Jul 2024	10 days	Derek Lamb

Effectiveness Reviews

Date	Reviewer	Memo
26 Jun 2023	Derek Lamb	First Run 24 Sep 2014 Last Run 24 Mar 2023 Number Runs 35 Usually Completed with 2 Updates 88.57 % of the time - 100% would be a Perfect Score Usually Completed within 3 Days 28.57 % of the time - Rating subject to Process Source Date Updates Issue# 6 (17.14%) Days to Complete 1 =># 3 (8.57%) Days to Complete 16 =># 3 (8.57%) Days to Complete 48 =># 2 (5.71%) Days to Complete 7 =># 2 (5.71%) Days to Complete 6 =># 2 (5.71%) Days to Complete 10 =># 1 (2.86%) Days to Complete 0 =># 1 (2.86%) Days to Complete 21 =># 1 (2.86%) Days to Complete 9 =># 1 (2.86%) Days to Complete 5 =># 1 (2.86%) Days to Complete 14 =># 1 (2.86%) Days to Complete 15 =># 1 (2.86%) Days to Complete 203 =># 1 (2.86%) Days to Complete 330 =># 1 (2.86%) Days to Complete 127 =># 1 (2.86%) Days to Complete 217 =># 1 (2.86%)

Management Review

Viamed - ISO and Compliance Controller

16 May 2023

Derek Lamb

Days to Complete 139 =># 1 (2.86%)
Days to Complete 56 =># 1 (2.86%)
Days to Complete 50 =># 1 (2.86%)
Days to Complete 29 =># 1 (2.86%)
Days to Complete 279 =># 1 (2.86%)
Days to Complete 35 =># 1 (2.86%)

First Run 24 Sep 2014
Last Run 24 Mar 2023
Number Runs 35
Usually Completed with 2 Updates 88.57
% of the time - 100% would be a Perfect
Score
Usually Completed within 3 Days 28.57 %
of the time - Rating subject to Process
Source Date
Updates
Issue# 6 (17.14%)
Days to Complete 1 =># 3 (8.57%)
Days to Complete 16 =># 3 (8.57%)
Days to Complete 48 =># 2 (5.71%)
Days to Complete 7 =># 2 (5.71%)
Days to Complete 6 =># 2 (5.71%)
Days to Complete 10 =># 1 (2.86%)
Days to Complete 0 =># 1 (2.86%)
Days to Complete 21 =># 1 (2.86%)
Days to Complete 9 =># 1 (2.86%)
Days to Complete 5 =># 1 (2.86%)
Days to Complete 14 =># 1 (2.86%)
Days to Complete 15 =># 1 (2.86%)
Days to Complete 203 =># 1 (2.86%)
Days to Complete 330 =># 1 (2.86%)
Days to Complete 127 =># 1 (2.86%)
Days to Complete 217 =># 1 (2.86%)
Days to Complete 139 =># 1 (2.86%)
Days to Complete 56 =># 1 (2.86%)
Days to Complete 50 =># 1 (2.86%)
Days to Complete 29 =># 1 (2.86%)
Days to Complete 279 =># 1 (2.86%)
Days to Complete 35 =># 1 (2.86%)

16 May 2023

Derek Lamb

First Run 24 Sep 2014
Last Run 24 Mar 2023
Number Runs 35
Usually Completed with 2 Updates 88.57
% of the time - 100% would be a Perfect
Score
Usually Completed within 3 Days 28.57 %
of the time - Rating subject to Process
Source Date
Updates
Issue# 6 (17.14%)
Days to Complete 1 =># 3 (8.57%)
Days to Complete 16 =># 3 (8.57%)
Days to Complete 48 =># 2 (5.71%)
Days to Complete 7 =># 2 (5.71%)
Days to Complete 6 =># 2 (5.71%)
Days to Complete 10 =># 1 (2.86%)
Days to Complete 0 =># 1 (2.86%)
Days to Complete 21 =># 1 (2.86%)
Days to Complete 9 =># 1 (2.86%)
Days to Complete 5 =># 1 (2.86%)
Days to Complete 14 =># 1 (2.86%)

Management Review

Viamed - ISO and Compliance Controller

Days to Complete 15 =># 1 (2.86%)
Days to Complete 203 =># 1 (2.86%)
Days to Complete 330 =># 1 (2.86%)
Days to Complete 127 =># 1 (2.86%)
Days to Complete 217 =># 1 (2.86%)
Days to Complete 139 =># 1 (2.86%)
Days to Complete 56 =># 1 (2.86%)
Days to Complete 50 =># 1 (2.86%)
Days to Complete 29 =># 1 (2.86%)
Days to Complete 279 =># 1 (2.86%)
Days to Complete 35 =># 1 (2.86%)

16 May 2023

Derek Lamb

First Run 24 Sep 2014
Last Run 24 Mar 2023
Number Runs 35
Usually Completed with 2 Updates 88.57
% of the time - 100% would be a Perfect
Score
Usually Completed within 3 Days 28.57 %
of the time - Rating subject to Process
Source Date
Updates
Issue# 6 (17.14%)
Days to Complete 1 =># 3 (8.57%)
Days to Complete 16 =># 3 (8.57%)
Days to Complete 48 =># 2 (5.71%)
Days to Complete 7 =># 2 (5.71%)
Days to Complete 6 =># 2 (5.71%)
Days to Complete 10 =># 1 (2.86%)
Days to Complete 0 =># 1 (2.86%)
Days to Complete 21 =># 1 (2.86%)
Days to Complete 9 =># 1 (2.86%)
Days to Complete 5 =># 1 (2.86%)
Days to Complete 14 =># 1 (2.86%)
Days to Complete 15 =># 1 (2.86%)
Days to Complete 203 =># 1 (2.86%)
Days to Complete 330 =># 1 (2.86%)
Days to Complete 127 =># 1 (2.86%)
Days to Complete 217 =># 1 (2.86%)
Days to Complete 139 =># 1 (2.86%)
Days to Complete 56 =># 1 (2.86%)
Days to Complete 50 =># 1 (2.86%)
Days to Complete 29 =># 1 (2.86%)
Days to Complete 279 =># 1 (2.86%)
Days to Complete 35 =># 1 (2.86%)

Process ID #7981 — Review Process Updates For Risk To Systems

Last Reviewed: 26 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

Management Review

Viamed - ISO and Compliance Controller

Risk Assessment

Risk Item	Notes / Value	Last Updated
Input to the Process	Intrastats processes	Helen Lamb 30 Dec 2021
Outputs to the Process	Up to date system regularly reviewed	Helen Lamb 30 Dec 2021
Risks to the Process	Monthly review could be missed changes to process could be missed	Helen Lamb 30 Dec 2021
Steps to Minimise Process Risks	regular issues and reviews	Helen Lamb 30 Dec 2021
Scope / Definition of Process / Objective	To review monthly any changes, to any processes, for risks to ISO systems.	Helen Lamb 30 Dec 2021
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 30 Dec 2021
Severity of Risk (1-5)	1.Negligible	Derek Lamb 30 Dec 2021
Measurable Objective	completed issues and up to date list	Helen Lamb 30 Dec 2021
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 30 Dec 2021
Verification / Effectiveness	This task is verified for effectiveness during internal rolling audit issues.	Helen Lamb 30 Dec 2021
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 30 Dec 2021
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

- 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 Task #1104

Subject: Review Process Updates For Risk To Systems

Target User: Derek Lamb

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

Notes:

System Generated

Task To be Completed To Review monthly any changes to running processes for risks to ISO systems.

Review the Updated Process Screen and review for any associated risks, and confirm the updated process is still effective to its objective.

Rolling Audit #1105

Subject: Review Process Updates For Risk To Systems

Management Review

Viamed - ISO and Compliance Controller

Target User: Helen Lamb

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

Notes:

System Generated Audit To be Completed To Review monthly any changes to running processes for risks to ISO systems.

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
395255	Review Process Updates For Risk To Systems (1104)	22 Apr 2026	23 Apr 2026	1 day	Derek Lamb
392501	Review Process Updates For Risk To Systems (1104)	23 Mar 2026	02 Apr 2026	10 days	Derek Lamb
389724	Review Process Updates For Risk To Systems (1104)	23 Feb 2026	02 Mar 2026	7 days	Derek Lamb
386570	Review Process Updates For Risk To Systems (1104)	22 Jan 2026	23 Jan 2026	1 day	Derek Lamb
384075	Review Process Updates For Risk To Systems (1104)	22 Dec 2025	29 Dec 2025	7 days	Derek Lamb
381582	Review Process Updates For Risk To Systems (1104)	24 Nov 2025	27 Nov 2025	3 days	Derek Lamb
379711	Review Process Updates For Risk To Systems (1105)	03 Nov 2025	06 Nov 2025	3 days	Helen Lamb
378776	Review Process Updates For Risk To Systems (1104)	22 Oct 2025	30 Oct 2025	8 days	Derek Lamb
375881	Review Process Updates For Risk To Systems (1104)	22 Sep 2025	22 Sep 2025	0 days	Derek Lamb
373396	Review Process Updates For Risk To Systems (1104)	22 Aug 2025	28 Aug 2025	6 days	Derek Lamb
370449	Review Process Updates For Risk To Systems (1104)	22 Jul 2025	24 Jul 2025	2 days	Derek Lamb
367790	Review Process Updates For Risk To Systems (1104)	23 Jun 2025	26 Jun 2025	3 days	Derek Lamb
365019	Review Process Updates For Risk To Systems (1104)	22 May 2025	29 May 2025	7 days	Derek Lamb
362152	Review Process Updates For Risk To Systems (1104)	22 Apr 2025	24 Apr 2025	2 days	Derek Lamb
359424	Review Process Updates For Risk To Systems (1104)	24 Mar 2025	25 Mar 2025	1 day	Derek Lamb
356384	Review Process Updates For Risk To Systems (1104)	24 Feb 2025	28 Feb 2025	4 days	Derek Lamb
353236	Review Process Updates For Risk To Systems (1104)	22 Jan 2025	23 Jan 2025	1 day	Derek Lamb
350408	Review Process Updates For Risk To Systems (1104)	23 Dec 2024	27 Dec 2024	4 days	Derek Lamb

Management Review

Viamed - ISO and Compliance Controller

347651	Review Process Updates For Risk To Systems (1104)	22 Nov 2024	22 Nov 2024	0 days	Derek Lamb
345632	Review Process Updates For Risk To Systems (1105)	01 Nov 2024	11 Nov 2024	10 days	Helen Lamb

Process ID #7888 — Review Processes Linked To VOPs And Audits

Last Reviewed: 28 Jul 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	Intrastats Processes To Audits and VOPs Screen	Derek Lamb 24 Oct 2017
Outputs to the Process	All active Processes are linked to Audits and Vops	Derek Lamb 24 Oct 2017
Risks to the Process	process can go un-monitored	Derek Lamb 24 Oct 2017
Steps to Minimise Process Risks	rolling task to link appropriately	Derek Lamb 24 Oct 2017
Scope / Definition of Process / Objective	Ensure All Sub Processes are linked to a VOP and an Audit.	Derek Lamb 24 Oct 2017
Likelihood of Risk (1-5)	3.Occasional	Derek Lamb 24 Oct 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 24 Oct 2017
Measurable Objective	review list	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=3, Severity=1)	

Interested Parties

- Internal Systems

Linked Companies

- VST
- Viamed Properties
- Viamed
- Vandagraph

Trained Staff (2)

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

Associated Documents

Management Review

Viamed - ISO and Compliance Controller

- 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 Task #818

Subject: Review Processes Linked To VOPs And Audits

Target User: Derek Lamb

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

Notes:

System GeneratedTask To be Completed Ensure All Sub Processes are linked to a VOP and an Audit.

Document index File Groups

Intrastats Processes To Audits and VOPs Screen

Rolling Audit #819

Subject: Review Processes Linked To VOPs And Audits

Target User: Helen Lamb

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

Notes:

System Generated** Audit Review ** Ensure the task is being done and check no blanks in the system

Task To be Completed Ensure All Sub Processes are linked to a VOP and an Audit. Intrastats Processes To Audits and VOPs Screen

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
395515	Review Processes Linked To VOPs And Audits (818)	24 Apr 2026	30 Apr 2026	6 days	Derek Lamb
392638	Review Processes Linked To VOPs And Audits (818)	24 Mar 2026	02 Apr 2026	9 days	Derek Lamb
389853	Review Processes Linked To VOPs And Audits (818)	24 Feb 2026	02 Mar 2026	6 days	Derek Lamb
386863	Review Processes Linked To VOPs And Audits (818)	26 Jan 2026	29 Jan 2026	3 days	Derek Lamb
384247	Review Processes Linked To VOPs And Audits (818)	24 Dec 2025	02 Jan 2026	9 days	Derek Lamb
382587	Review Processes Linked To VOPs And Audits (819)	04 Dec 2025	02 Jan 2026	29 days	Helen Lamb
381572	Review Processes Linked To VOPs And Audits (818)	24 Nov 2025	27 Nov 2025	3 days	Derek Lamb
378975	Review Processes Linked To VOPs And Audits (818)	24 Oct 2025	30 Oct 2025	6 days	Derek Lamb
376113	Review Processes Linked To VOPs And Audits (818)	24 Sep 2025	25 Sep 2025	1 day	Derek Lamb
373501	Review Processes Linked To VOPs And Audits (818)	25 Aug 2025	28 Aug 2025	3 days	Derek Lamb

Management Review

Viamed - ISO and Compliance Controller

370706	Audits (818) Review Processes Linked To VOPs And Audits (818)	24 Jul 2025	24 Jul 2025	0 days	Derek Lamb
367910	Review Processes Linked To VOPs And Audits (818)	24 Jun 2025	26 Jun 2025	2 days	Derek Lamb
365278	Review Processes Linked To VOPs And Audits (818)	26 May 2025	29 May 2025	3 days	Derek Lamb
362430	Review Processes Linked To VOPs And Audits (818)	24 Apr 2025	02 May 2025	8 days	Derek Lamb
359412	Review Processes Linked To VOPs And Audits (818)	24 Mar 2025	25 Mar 2025	1 day	Derek Lamb
356374	Review Processes Linked To VOPs And Audits (818)	24 Feb 2025	28 Feb 2025	4 days	Derek Lamb
353562	Review Processes Linked To VOPs And Audits (818)	24 Jan 2025	30 Jan 2025	6 days	Derek Lamb
350535	Review Processes Linked To VOPs And Audits (818)	24 Dec 2024	27 Dec 2024	3 days	Derek Lamb
348754	Review Processes Linked To VOPs And Audits (819)	04 Dec 2024	12 Dec 2024	8 days	Helen Lamb
347785	Review Processes Linked To VOPs And Audits (818)	25 Nov 2024	04 Dec 2024	9 days	Derek Lamb

Process ID #7977 — Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting

Last Reviewed: 08 Aug 2025 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	AgendaMeetings and management review can also raise areas that have been missed	Helen Lamb 11 Nov 2021
Outputs to the Process	A comprehensive management review / Board meeting agenda and therefore meeting	Helen Lamb 11 Nov 2021
Risks to the Process	That we will miss a header and something important will not be discussed.	Helen Lamb 11 Nov 2021
Steps to Minimise Process Risks	Regular reviews and discussions in the Meeting itself, to ensure the agenda is up to date and relevant.	Helen Lamb 11 Nov 2021
Scope / Definition of Process /	To review the Agenda of the Management	Helen Lamb 11 Nov 2021

Management Review

Viamed - ISO and Compliance Controller

Objective	review. Make sure no headers are missed that should be being discussed. Make sure Objectives are appropriate and effective.	
Likelihood of Risk (1-5)	1. Improbable	Helen Lamb 13 Nov 2021
Severity of Risk (1-5)	2. Minor	Helen Lamb 11 Nov 2021
Measurable Objective	A completed issue Management review carried out effectively.	Helen Lamb 11 Nov 2021
Training Method Required	Hands on by experienced member of staff	Helen Lamb 11 Nov 2021
Verification / Effectiveness	This Management review is assessed for effectiveness in detail by BSI when they do their annual visit. Reviewed by the board during and after the management review.	Helen Lamb 11 Nov 2021
Covid / Pandemic Notes	This is not affected by Covid 19 or any other national or international crisis	Helen Lamb 11 Nov 2021
Risk / Benefit Report	The addition of this task is aimed at reducing the risk of missing a header. If a header is missed the risk would be to miss discussing something important.	Helen Lamb 11 Nov 2021
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 Helen Lamb)
- Helen Lamb (trained by Helen 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 Task #1100

Subject: Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting

Target User: Helen Lamb

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

Notes:

System Generated Task To be Completed

Review the Agenda of the Management review for Viamed and VST and make sure we do not need any other headers and to check that we have up to date and appropriate objectives. Once reviewed check with the Managing directors that they do not have anything further that should be added.

Rolling Audit #1101

Subject: Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting

Target User: Derek Lamb

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

Notes:

Management Review

Viamed - ISO and Compliance Controller

System Generated Audit of the task

Check it has been completed and check you have been consulted by the member of staff carrying out the task

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
376499	Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting (1101)	29 Sep 2025	09 Oct 2025	10 days	Derek Lamb
371677	Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting (1100)	04 Aug 2025	01 Sep 2025	28 days	Derek Lamb
342309	Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting (1101)	30 Sep 2024	11 Nov 2024	42 days	Derek Lamb
337146	Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting (1100)	05 Aug 2024	22 Nov 2024	109 days	Derek Lamb

Process ID #7828 — Review The Quality Policy Viamed

Last Reviewed: 28 Jul 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	Rolling Issue to trigger a review, Quality policy in the system	Derek Lamb 16 Sep 2017
Outputs to the Process	Completed Task to history and document marked as reviewed or marked for update and issue left alive.	Derek Lamb 16 Sep 2017
Risks to the Process	That the policy will go out of date	Helen Lamb 22 Jul 2019
Steps to Minimise Process Risks	Keep up to date with issues.	Helen Lamb 22 Jul 2019
Scope / Definition of Process / Objective	To review the Quality policy and check it is still valid and upto date.	Derek Lamb 16 Sep 2017

Management Review

Viamed - ISO and Compliance Controller

Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 16 Sep 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 16 Sep 2017
Measurable Objective	Check rolling issues are completed within terms.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	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 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=1)	

Linked ISO Sections

- 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: 5.3
- 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: 5.1.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 6.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.2.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 6.2.1

Interested Parties

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

Linked Companies

- Viamed

Trained Staff (2)

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

Associated Documents

- Audit 20 Process verification to Management Viamed (Doc ID: 159389)
- Audit 20 Process verification to Management VST (Doc ID: 159391)
- VM3COP00.00 VOP00.00 Viamed Quality Statement policy and objectives (Doc ID: 164833)
- VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records (Doc ID: 120321)

Management Review

Viamed - ISO and Compliance Controller

Rolling Task #723

Subject: Review The Quality Policy Viamed
Target User: Derek Lamb
Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:
System Generated
Task To be Completed

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
373496	Review The Quality Policy Viamed (723)	25 Aug 2025	02 Oct 2025	38 days	Derek Lamb
339136	Review The Quality Policy Viamed (723)	27 Aug 2024	08 Jan 2025	134 days	Derek Lamb

Process ID #7827 — Review The Quality Policy VST

Last Reviewed: 28 Jul 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	Rolling Issue to trigger a review, Quality policy in the system	Derek Lamb 16 Sep 2017
Outputs to the Process	Completed Task to history and document marked as reviewed or marked for update and issue left alive.	Derek Lamb 16 Sep 2017
Risks to the Process	that policy will go out of date	Helen Lamb 22 Jul 2019
Steps to Minimise Process Risks	Keep up to date with issues.	Helen Lamb 22 Jul 2019
Scope / Definition of Process / Objective	To review the Quality policy and check it is still valid and upto date.	Derek Lamb 16 Sep 2017
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 16 Sep 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 16 Sep 2017
Measurable Objective	Check rolling issues are completed within terms.	Helen Lamb 22 Jul 2019
Training Method Required	Procedural , Required Reading and Hands on	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 and management review meeting.	Helen Lamb 26 Oct 2020

Management Review

Viamed - ISO and Compliance Controller

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)	

Linked ISO Sections

- 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 ISO9001:2015: 4.4.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.1.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.2.1
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 5.2.2
- Quality Management System Route Map to Documents and Procedures Viamed Ltd ISO9001:2015: 6.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.1.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 5.2.2
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 6.2.1
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.1.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.3.2

Interested Parties

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

Linked Companies

- VST

Trained Staff (2)

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

Associated Documents

- Audit 20 Process verification to Management Viamed (Doc ID: 159389)
- Audit 20 Process verification to Management VST (Doc ID: 159391)
- VM3COP00.00 VOP00.00 VST Quality Statement policy and objectives (Doc ID: 164813)
- VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records (Doc ID: 120321)

Rolling Task #301

Subject: Review the Quality policy VST

Target User: Derek Lamb

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

Notes:

System Generated

Review the Quality policy and check it still meets the objectives

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
373457	Review the Quality policy VST (301)	25 Aug 2025	06 Feb 2026	165 days	Derek Lamb
339089	Review the Quality policy VST (301)	27 Aug 2024	08 Jan 2025	134 days	Derek Lamb

Management Review

Viamed - ISO and Compliance Controller

Process ID #7979 — Review The Template Of The QC 21 Form To Ensure It Is Current And Valid

Last Reviewed: 28 Jul 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	QC 21 Form BSI Assessments	Helen Lamb 12 Nov 2021
Outputs to the Process	Completed and compliant forms	Helen Lamb 12 Nov 2021
Risks to the Process	that we will miss sections that we need to be effective	Helen Lamb 12 Nov 2021
Steps to Minimise Process Risks	regular reviews and assessments	Helen Lamb 12 Nov 2021
Scope / Definition of Process / Objective	To review the QC 21 form to make sure it is fit for purpose and covers all the areas we need to assess when filling in this form	Helen Lamb 12 Nov 2021
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 12 Nov 2021
Severity of Risk (1-5)	2.Minor	Helen Lamb 12 Nov 2021
Measurable Objective	To ensure we have a valid and up to date form that can be used to accurately and effectively review Non Conformances, internally and externally. That includes risk and effectiveness.	Helen Lamb 12 Nov 2021
Training Method Required	Hands on with experienced members of staff	Helen Lamb 12 Nov 2021
Verification / Effectiveness	these will be verified each time they are use and when we submit them to BSI they will also review the form as well as the contents of it.	Helen Lamb 12 Nov 2021
Covid / Pandemic Notes	this in not affected by Covid 19 pandemic or any national or international crisis	Helen Lamb 12 Nov 2021
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
- Government E.G. HMRC

Linked Companies

- Viamed
- VST

Trained Staff (2)

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

Associated Documents

Management Review

Viamed - ISO and Compliance Controller

- Audit 18 Management Review Viamed (Doc ID: 159471)
- Audit 18 Management Review VST (Doc ID: 159473)
- QC 21 Non Conformance Form (Doc ID: 74728)
- VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd (Doc ID: 132118)

Rolling Task #1102

Subject: Review The Template Of The QC 21 Form To Ensure It Is Current And Valid

Target User: Derek Lamb

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

Notes:

System Generated Task To be Completed

To ensure we have a valid and up to date form that can be used to accurately and effectively review Non Conformances, internally and externally. That includes risk and effectiveness.

Have we got all areas needed covered in this form

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
370978	Review The Template Of The QC 21 Form To Ensure It Is Current And Valid (1102)	28 Jul 2025	04 Aug 2025	7 days	Derek Lamb
336469	Review The Template Of The QC 21 Form To Ensure It Is Current And Valid (1102)	29 Jul 2024	13 Aug 2024	15 days	Derek Lamb

Process ID #28 — Supplier Review

Last Reviewed: 09 Feb 2026 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	Supplier review intrastats screen, showing our current suppliers. Supplier websites for ISO certificates Email systems for supplier whom dont have certificates online.	Derek Lamb 22 Aug 2016
Outputs to the Process	Supplier Grading	Derek Lamb 22 Aug 2016
Risks to the Process	Supplier certificates go out of date, or they lose ISO standards and we're unaware	Derek Lamb 22 Aug 2016
Steps to Minimise Process Risks	rolling task to do the supplier review	Derek Lamb 22 Aug 2016
Scope / Definition of Process / Objective	Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.	Derek Lamb 22 Aug 2016
Likelihood of Risk (1-5)	1.Improbable	Derek Lamb 12 Jun 2017
Severity of Risk (1-5)	1.Negligible	Derek Lamb 12 Jun 2017

Management Review

Viamed - ISO and Compliance Controller

Measurable Objective	Check the supplier review page make sure none are more than a month out of date.	Helen Lamb 29 Aug 2018
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=1)	

Linked ISO Sections

- 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: 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 VST Ltd ISO9001:2015+A1: 9.1.3
- Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015+A1: 9.3.2

Interested Parties

- Supplier
- Physical Sites
- Internal Systems
- VST Supplier
- VST Supplier
- VST Supplier

Linked Companies

- Vandagraph
- Viamed
- Viamed Properties
- VST

Trained Staff (3)

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

Associated Documents

- Audit 05 Purchasing suppliers Viamed (Doc ID: 159433)
- Audit 05 Purchasing suppliers VST (Doc ID: 159435)
- VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection (Doc ID: 200924)
- VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market (Doc ID: 210961)

Rolling Task #15

Subject: Supplier Review

Target User: Derek Lamb

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

Notes:

System Generated

Need To do full Supplier Review.

Need to add to the review - getting supplier agreements added as a file, confirming they will notify us of changes and/or vigilance notifications.

Management Review

Viamed - ISO and Compliance Controller

Rolling Audit #610

Subject: Supplier Review

Target User: Helen Lamb

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

Notes:

System Generated*** AUDIT *** Ensure the Task is being Completed

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
388313	Supplier Review (610)	09 Feb 2026	10 Feb 2026	1 day	Helen Lamb
371304	Supplier Review (15)	31 Jul 2025	12 Sep 2025	43 days	Derek Lamb
355046	Supplier Review (610)	10 Feb 2025	13 Feb 2025	3 days	Helen Lamb
336693	Supplier Review (15)	31 Jul 2024	08 Aug 2024	8 days	Derek Lamb

Process ID #7998 — Verification Calibrated Equipment

Last Reviewed: 18 Nov 2025 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	Test equipment Calibration IndexDate sticker	Helen Lamb 12 Nov 2024
Outputs to the Process	Completed list and up to date calibrated equipment Equipment identified with a CE0 label and a date sticker	Helen Lamb 12 Nov 2024
Risks to the Process	Equipment missed from the list Goods could have been tested with equipment that has not been calibrated.Or the date may not be attached.	Helen Lamb 12 Nov 2024
Steps to Minimise Process Risks	regular reviews and checking of test equipment. Checking the equipment for a date label on calibration	Helen Lamb 12 Nov 2024
Scope / Definition of Process / Objective	Verify Equipment used is logged and up to date in the ISO calibration Index and that they have a date of calibration sticker on it.	Helen Lamb 12 Nov 2024
Likelihood of Risk (1-5)	1.Improbable	Helen Lamb 23 Feb 2022
Severity of Risk (1-5)	3.Serious	Helen Lamb 23 Feb 2022

Management Review

Viamed - ISO and Compliance Controller

Measurable Objective	Check the ISO calibration Index is up to date. Check the test areas for any Calibration equipment that does not have an ISO Calibration CE Sticker. Workshop, R and D room, Vandagraph areas, QA bench. Visual check for the date sticker on all calibrated equipment.	Helen Lamb 12 Nov 2024
Training Method Required	Hands on Learning from experienced staff	Helen Lamb 23 Feb 2022
Verification / Effectiveness	This task is verified for effectiveness during internal rolling audit issues.	Helen Lamb 23 Feb 2022
Covid / Pandemic Notes	This process is not affected by Covid 19 or other extreme national or international circumstance / crisis.	Helen Lamb 23 Feb 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=3)	

Interested Parties

- Internal Systems
- Physical Sites
- Customer
- Supplier
- VST OEM Customers
- VST Supplier

Linked Companies

- Viamed
- Vandagraph
- VST

Trained Staff (2)

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

Rolling Task #1141

Subject: Verification Calibrated Equipment
Target User: Helen Lamb
Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Notes:

System Generated Task To be Completed

Verify Equipment used is logged and upto date in the ISO calibration Index.

Check Test areas for any Calibration equipment that does not have an ISO Calibration CE Sticker.

Rolling Audit #1142

Subject: Verification Calibrated Equipment
Target User: Derek Lamb
Recurrence: 12 Month(s) 0 Week(s) 0 Day(s)

Management Review

Viamed - ISO and Compliance Controller

Notes:

System Generated Task To be Completed Verify Equipment used is logged and up to date in the ISO calibration Index

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

ID	Subject	Created	Completed	Days to Complete	Investigated By
396904	Verification Calibrated Equipment (1141)	11 May 2026	14 May 2026	3 days	Helen Lamb
381129	Verification Calibrated Equipment (1142)	18 Nov 2025	20 Nov 2025	2 days	Derek Lamb
363990	Verification Calibrated Equipment (1141)	12 May 2025	15 May 2025	3 days	Helen Lamb
347197	Verification Calibrated Equipment (1142)	18 Nov 2024	21 Nov 2024	3 days	Derek Lamb

Responsibility-Only Processes (8)

These processes represent allocated responsibilities only - no rolling task or audit is required, so they are excluded from the main report metrics and conclusion.

- **#5889:** Audit And Task - Audit (last reviewed: 13 Sep 2024)
- **#7172:** CE Technical Files (last reviewed: 02 Jan 2024)
- **#29:** CMDCAS Updates And Licences (last reviewed: 29 Oct 2021)
- **#24:** Compliance ISO Standards (last reviewed: 11 Nov 2021)
- **#7069:** Corrective Actions (last reviewed: 10 Oct 2017)
- **#7200:** ISO Issues (last reviewed: 25 Oct 2017)
- **#6865:** Non Conformance Effectiveness (last reviewed: 10 Oct 2017)
- **#7264:** VST Management Meeting Non Conformance Issues (last reviewed: 28 Jul 2025)

Conclusion / Executive Summary

Auto-calculated summary of findings across the report.

Coverage

- 1 roles reviewed
- 25 active processes reviewed
- 8 responsibility-only processes (excluded from metrics, listed per role)

Key Risks

- 1 overdue rolling task(s) / audit(s) across all roles

Overdue Reviews

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

Dependency Warnings

- [ISO and Compliance Controller] Derek Lamb linked to 100% (25 of 25) of role processes - single point of failure risk

Missing Audits

Management Review

Viamed - ISO and Compliance Controller

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

Missing Measurable Objectives

- 1 process(es) missing measurable objective

Trained Staff Coverage

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

Process Maturity Overview

- 2 of 25 processes (8%) 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
ISO and Compliance Controller	25	1	1	8	0	1	16

End of Management Review Report - Viamed