

Document VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market Revision ID210955

Suggested Upload Document Name: **Risk Assesment For Updating Document ID210955**

Completed by [Derek Lamb](#) 16 Feb 2026

Reason for Risk Assesment

Fixed Title from saying Viamed - no actual document updated so, no risk to iso system

Document VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market Revision ID210955 Is linked to the Following Standards and processes

Risk Assesment ID210955	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement required
210955Q0	Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q1	Viamed Ltd ISO13485:2016 Section: 4.1.3 Quality management system For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q2	Viamed Ltd ISO13485:2016 Section: 5.6.1 General The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q3	Viamed Ltd ISO13485:2016 Section: 5.6.2 General Review input The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q4	Viamed Ltd ISO13485:2016 Section: 8.1 General The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to: a) demonstrate conformity of product; b) ensure conformity of the quality management system;	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement required

c) maintain the effectiveness of the quality management system.
This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

1.Negligible ▾
Action Required:
No Action Required

210955Q5	<p>Viamed Ltd ISO13485:2016 Section: 8.2.1 Feedback As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented. The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.</p>	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required
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210955Q6	<p>Viamed Ltd ISO13485:2016 Section: 8.2.4 Internal audit The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.</p>	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required
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210955Q7	<p>Viamed Ltd ISO13485:2016 Section: 8.2.5 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.</p>	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required
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210955Q8	<p>Viamed Ltd ISO13485:2016 Section: 8.4 Analysis of data The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements;</p>	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required
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c) characteristics and trends of processes and product including opportunities for improvement;
d) suppliers;
e) audits;
f) service reports, as appropriate.
If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).

210955Q9	<p>VST Ltd ISO9001:2015+A1 Section: 6.2.1</p> <p>The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall:</p> <ul style="list-style-type: none"> a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. <p>The organization shall maintain documented information on the quality objectives</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q10	<p>VST Ltd ISO9001:2015+A1 Section: 8.5.5</p> <p>Post-delivery activities</p> <p>The organization shall meet requirements for post-delivery activities associated with the products and services.</p> <p>In determining the extent of post-delivery activities that are required, the organization shall consider:</p> <ul style="list-style-type: none"> a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. <p>NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q11	<p>VST Ltd ISO9001:2015+A1 Section: 9.1.1</p> <p>General</p> <p>The organization shall determine:</p> <ul style="list-style-type: none"> a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated. <p>The organization shall evaluate the performance and the effectiveness of the quality management system.</p> <p>The organization shall retain appropriate documented information as evidence of the results.</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q12	<p>VST Ltd ISO9001:2015+A1 Section: 9.1.2</p> <p>Customer satisfaction</p> <p>The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.</p> <p>NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q13	<p>VST Ltd ISO9001:2015+A1 Section: 9.1.3</p> <p>Analysis and evaluation</p> <p>The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.</p> <p>The results of analysis shall be used to evaluate:</p> <ul style="list-style-type: none"> a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. <p>NOTE Methods to analyse data can include statistical techniques.</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>

<p>210955Q14 VST Ltd ISO9001:2015+A1 Section: 9.2.1</p> <p>The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:</p> <p>a) conforms to:</p> <ol style="list-style-type: none"> 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained. 	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q15 VST Ltd ISO9001:2015+A1 Section: 9.2.2</p> <p>The organization shall:</p> <ol style="list-style-type: none"> a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. <p>NOTE See ISO 19011 for guidance.</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q16 VST Ltd ISO9001:2015+A1 Section: 9.3.1</p> <p>General</p> <p>Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q17 VST Ltd ISO9001:2015+A1 Section: 9.3.2</p> <p>Management review inputs</p> <p>9.3.2 Management review inputs</p> <p>The management review shall be planned and carried out taking into consideration:</p> <ol style="list-style-type: none"> a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) information on the performance and effectiveness of the quality management system, including trends in: <ol style="list-style-type: none"> 1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement. 	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q18  Process22</p> <p>Company Polycys</p> <p>Ensure the company polycys are still current and upto date</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>No Action</p>
<p>210955Q19  Process23</p> <p>Company Objectives</p> <p>Ensure the company Objects are still current and upto date</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q20  Process55</p> <p>Business Continuity Plan</p> <p>Business Continuity Plan</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to</p>	<p>Notes On Risk / Benefits statement required</p>

			Update 1.Negligible ▾ Action Required: No Action Required	No Action
210955Q21	Process7846 ISO System Management Review Viamed To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q22	Process7834 Financial Review The review the Financial requirements	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q23	Process27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q24	Process26 Company Resources Overview of the Company using various data Reporting Screens	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q25	Process38 Audits Up to Date and Confirm next years Audit schedule Management oversight of Internal Tasks and Audits Issue(s). Review the responses to Tasks and Audits. ensure they are being fulfilled and completed. Ensure Audits performed indendantly of audit area Ensure All ISO Sections linked to an Audit - QC 17 Route Map	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q26	Process5877 Review Company Data To review the numbers of various departments. Showing increasing / reducing staff requirements Check Audit Roles Titles and Processes in Employee Roles and Titles. Check the Page for Red Crosses and potentially missing objectives	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q27	Process7070 Management Review To discuss any problems, to assess work load and staffing. To review issues.	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q28	Process5887 Review ISO/EN Documents To Keep Products and Services up-to date with current regulations and standards	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement required No Action

210955Q29	<p>Process5889 Audit And Task - Audit To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="4.Critical"/> Action Required: No Action Required	Notes On Risk / Benefits statement required <div style="border: 1px solid black; height: 50px;"></div>
210955Q30	<p>Process6866 Internal Process Verification Complete Systems Review Review the Internal Process and Verification`s are suitable for the current standards</p> <p>PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required <div style="border: 1px solid black; height: 50px;"></div>
210955Q31	<p>Process7071 Post Market Surveillance 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.</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="3.Occasional"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action <div style="border: 1px solid black; height: 50px;"></div>
210955Q32	<p>Process7093 BSI Audits Calander Review of outstanding Audits</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action <div style="border: 1px solid black; height: 50px;"></div>
210955Q33	<p>Process7172 CE Technical Files Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required <div style="border: 1px solid black; height: 50px;"></div>
210955Q34	<p>Process7138 Non Conformance Issues Any New QC21 Forms To review any new QC 21 Forms Check existing forms for corrective actions and effectiveness</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action <div style="border: 1px solid black; height: 50px;"></div>
210955Q35	<p>Process7808 Ensure All Invoice Correctly Tagged To find and Tag any sales that are removed from commissions, as they are break even products for relationships purposes</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action <div style="border: 1px solid black; height: 50px;"></div>
210955Q36	<p>Process7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems.</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement required <div style="border: 1px solid black; height: 50px;"></div>
210955Q37	<p>Process7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats.</p> <p>Process no longer required with end of Opera</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required <div style="border: 1px solid black; height: 50px;"></div>

<p>210955Q38 Process57 Temporary Stock Notices To Review Memos on Stock references tagged as Temporary</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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<p>210955Q39 Process5854 Stock FAQ Admin List To update and maintain the Stock FAQ list</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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<p>210955Q40 Process6871 ISO14001 Environmental management systems Not yet Applied Rolling Issue to see if we should apply this standard in the future</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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<p>210955Q41 Process7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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<p>210955Q42 Process28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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<p>210955Q43 Process7879 Software Validation Scheduled Tasks And Audits To check the Scheduled Tasks and Audits is working as Intended. To also Check the Out of Date documents is working as Intended.</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action</p>
<p>210955Q44 Process7876 Maintain Update Of ISO Route Maps To review Route map VIAMED 13485:2016 and VST 9001:2015 See if a new Summary sheet needs producing, print new PDF, and upload on top of the old summary</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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<p>210955Q45 Process7878 Review Possible Upcoming Regulation Changes Review possible legal / regulator changes that might affect Viamed / VST</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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<p>210955Q46 Process7885 Audit 04 Accounts and Finance Viamed Carry out Audit 04 Accounts for Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
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210955Q47	<p>Process7837 Review External Parties Influencing The QMS VST / Viamed To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q48	<p>Process7888 Review Processes Linked To VOPs And Audits Ensure All Sub Processes are linked to a VOP and an Audit.</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q49	<p>Process7965 VST Feedback Enter Feedback from VST customer or Suppliers in the the Feedback headers Both Positive and Negative feedback to be logged</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q50	<p>Process7964 Check Roles And Tasks For Incomplete Data To check the Roles and tasks tables for any gaps /red crosses Fill in the missing information where needed.</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q51	<p>Process7877 Disaster Planning To Plan for disaster</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q52	<p>Process7980 Review Gov Website For Applicable Required Standards ISO9001 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</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q53	<p>Process7972 ISO System Management Review Vst To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13 *Note was linked to Viamed management headers relinked in 2025</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q54	<p>Process7973 VST Product Performance - Customers To produce Product performance report showing 2 years of returns. Which we can use to send to customers.</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q55	<p>Process7974 VST Product Performance - Suppliers To produce Product performance report for Suppliers PMS Files</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement required

			1.Negligible Action Required: No Action Required	No Action
210955Q56	<p>Process7977</p> <p>Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting</p> <p>To review the Agenda of the Management review. Make sure no headers are missed that should be being discussed.</p> <p>Make sure Objectives are appropriate and effective.</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>The addition of this task is aimed at reducing the risk of missing a header. If a header missed the risk would be to discussing something importa</p>
210955Q57	<p>Process7978</p> <p>Regulatory Requirements and Review of QC21 form template</p> <p>To Regulatory Requirements and a Review of QC21 form template. To ensure they are up to date to the current standards</p> <p>review Qc 21 Form to ensure it is still appropriate and valid</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>3.Occasional</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>No Action
</p>
210955Q58	<p>Process7981</p> <p>Review Process Updates For Risk To Systems</p> <p>To review monthly any changes, to any processes, for risks to ISO systems.</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>No Action
</p>
210955Q59	<p>Process8012</p> <p>VAT Return Viamed Properties</p> <p>VAT return is submitted to the HMRC through accounts software after the end of the quarter.</p> <p>The information for this is taken from the accounts package with some information from Intrastats</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>No Action
</p>
210955Q60	<p>Process7045</p> <p>Design and Development</p> <p>Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS 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 Carry out the Technical File PMS Form for Each OBL and Viamed Product Using procedure VM3COP27.11</p> <p>See VM3COP18</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q61	<p>Process7849</p> <p>Review Product Failures New Codes</p> <p>Review the Customer Returns and Review Product Failures New Codes</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>3.Occasional</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>No Action
</p>
210955Q62	<p>Process7830</p> <p>Review Q.A. Failures Report</p> <p>To review the Quantities of Failed product per Stock reference Passing through the Q.A. system</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>3.Serious</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>No Action
</p>
210955Q63	<p>Process8014</p> <p>Review VIAMED Product Feedback Positive</p> <p>Review VIAMED Product Feedback Positive</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p> <p>No Action
</p>

210955Q64	<p>Process8015 Review VST Product Feedback Positive Review VST Product Feedback Positive</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q65	<p>Process8016 Review VIAMED Customer Feedback Positive Review Positive Customer Feedback</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q66	<p>Process8017 Review VST Customer Feedback Positive Review VST Customer Feedback Positive</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q67	<p>Process8018 Wednesday Meeting Rolling Issue for Notes During the Weekly Meeting To discuss any problems, to assess work load and staffing. To review issues.</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q68	<p>Process8019 Audit 04 Accounts And Finance VST Carry out Audit 04 Accounts for VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q69	<p>Process8036 Future Issues Review To review any new rolling future issues check they have a processed it is linked to. Make sure it not duplicated</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q70	<p>Process8072 Quartly Sales And Marketing Meeting Due Quarterly Sales and Marketing Meeting Due BSI REgulation meeting required, To Include UK Sales Staff, Export Sales Staff, and Sales Director</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q71	<p>Process8073 Quarterly Stock Meeting Due Quarterly Stock Meeting Due - Full Stock Meeting Due</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q72	<p>Process8089 Review Any Outstanding QC 21 Forms To Sign Off Review Any Outstanding QC 21 Forms. If completed, sign it off. Review it to make sure all parts are completed satisfactorily</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required There is a risk of an uncom form being missed. This proc is here to reduce the likeli of this ever happening.
Action</p>

210955Q73	<p>Process8094 Meeting With DL Just a heading to enable a rolling Task for Issues to link to a Meeting With DL</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q74	<p>ProcessProcess 7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file.</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q75	<p>ProcessProcess 27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits Current Known Risk that the task is missed that follow ups are missed Current Likly 3 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q76	<p>ProcessProcess 5889 Audit And Task - Audit To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits Current Known Risk non risk to process, Risk of not completing is Jobs / tasks can go not done Current Likly 4 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q77	<p>ProcessProcess 26 Company Resources Overview of the Company using various data Reporting Screens Current Known Risk Not enough resources to complete tasks Current Likly 3 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q78	<p>ProcessProcess 7830 Review Q.A. Failures Report To review the Quantities of Failed product per Stock reference Passing through the Q.A. system Current Known Risk That a high proportion of a product might fail QA and not be flagged Current Likly 3 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q79	<p>ProcessProcess 7828 Review The Quality Policy Viamed To review the Quality policy and check it is still valid and upto date. Current Known Risk That the policy will go out of date Current Likly 1 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q80	<p>ProcessProcess 7827 Review The Quality Policy VST To review the Quality policy and check it is still valid and upto date. Current Known Risk that policy will go out of date Current Likly 1 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q81	<p>ProcessProcess 7822 Review Oxylink Stock To check we have the stock available to supply our customer Oxylink. NOTE THIS PROCESS HAS BEEN STOPPED. Part number has been superseded Current Known Risk The we do not have the stock needed to satisfy the orders for</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required

this customer.
Current Likly 3 Current Frequency 1

210955Q82	<p>ProcessProcess 7797 Check Order Are Being Picked In Priority Order Check order are being picked in order of priority and date. Current Known Risk Orders going at before more urgent ones Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q83	<p>ProcessProcess 7761 Send VST Delivery Notifications Emailing Notifications of shipments Current Known Risk Limited risks, and if the email fails to get delivered the customer will still receive their shipment. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q84	<p>ProcessProcess 7760 Send Service Offers Send letters to existing customers to remind them that a service is due on their equipment Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q85	<p>ProcessProcess 7709 Delivered not Invoiced Ensure invoices are generated for shipped orders Current Known Risk Computer/network breakdown delivery is missed and remains un invoiced. Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q86	<p>ProcessProcess 7953 Vandagraph Delivery Notifications To Send Vandagraph Delivery notifications Current Known Risk task not carried out Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q87	<p>ProcessProcess 7691 Ship Sale Or Returns Review the sale or return shelf and ship those items. Current Known Risk Goods will be missed Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q88	<p>ProcessProcess 7690 Ship Repairs Review the Repairs completed shelf and ship those items that are ready for return to the customer. Current Known Risk That a repair will be missed Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q89	<p>ProcessProcess 7686 Thorough Checking Of Awaiting Action Tray - Priority 8s Check that outstanding orders with unresolved issues are being followed up and addressed Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q90	<p>ProcessProcess 7685 Repairs Ready For Invoice Process Invoice for completed repairs. Current Known Risk repair has errors on it Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required:</p>	<p>Notes On Risk / Benefits statement required No Action
</p>

No Action Required

210955Q91	<p>ProcessProcess 7684 Repairs Ready For Quote Process Repairs Ready For Quote Current Known Risk If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q92	<p>ProcessProcess 7683 Check Stock For Proforma To check that we have stock in for customer proformas. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q93	<p>ProcessProcess 7678 Check Catalog 360 Circle For Quotes And Orders Checking the Catalog 360 Circle website for outstanding orders or requests SYSTEM NO LONGER USED Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q94	<p>ProcessProcess 7674 Check Repairs Ready For Invoice List Review the repairs ready For invoice List in intrastats. Current Known Risk That repairs will be missed. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q95	<p>ProcessProcess 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates. Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q96	<p>ProcessProcess 7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems. Current Known Risk That there are duplicate orders o the system due to errors. Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q97	<p>ProcessProcess 6898 GHX Web Pricing To review the GHX Web Pricing Current Known Risk That the prices are in correct and we may have to let them have the old price if we have not up dated them Current Likly 1 Current Frequency 2</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
210955Q98	<p>ProcessProcess 5871 Check Sale Or Returns Review the Sale or Return list in intrastats. Ensure it is up to date. Current Known Risk That goods could be sent to a customer or goods returned but the list is not updated Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
210955Q99	<p>ProcessProcess 5876 E.Commerce Cardea And Multiquote To Collect E.Commerce Cardea And Multiquote Orders Current Known Risk Orders go unnoticed Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>

210955Q100	<p>Process 5872 Check Sale Or Returns Export Review the Sale or Return list in intrastats. Ensure it is up to date. Current Known Risk That goods could be sent to a customer or goods returned but the list is not updated Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q101	<p>Process 11 Distribution Of Post Distributing incoming post to correct person Current Known Risk Royal Mail fail to deliver post Current Likly 3 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q102	<p>Process 14 Fax Paper Ensuring that fax reports have been generated for both sent and received faxes and ensuring there is paper in the fax machine Current Known Risk Phone lines go down The paper tray is empty Current Likly 1 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q103	<p>Process 15 Filing and Archiving Paperwork to be filed in the correct order Current Known Risk Paperwork is filed incorrectly Current Likly 1 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q104	<p>Process 21 Office Sales Projects Ensuring office job list is being updated and completed Current Known Risk Office is short staffed or over worked Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q105	<p>Process 36 Emailing Of Invoices Invoices are emailed to customers Current Known Risk Computer or network failure Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q106	<p>Process 5875 Check Paypal For Orders Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q107	<p>Process 5882 Send Post To Humanmed Humanmed post is received, it needs to be forwarded to Humanmed UK Sales Manager HumanMed has Gone, tasks no longer required Current Known Risk Post is not sent Current Likly 4 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q108	<p>Process 5892 Checking EBay And Amazon For Orders And Messages Checking the eBay and Amazon accounts for orders that have not been emailed to the main inbox and checking to see if there are messages or questions. Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action

<p>210955Q109 Process 5893 Answering Website Questions Answering any questions that are asked via the website from within Intrastats</p> <p>PROCESS NO LONGER REQUIRED Web QUESTIONS NOW COME IN VIA shopify, and Email Current Known Risk Computer/network breakdown</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q110 Process 5894 Checking Of Active List Check the Active Back orders ensure no orders get missed Current Known Risk List is not reviewed and orders do not get shipped</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q111 Process 5895 Completing Office Job List Ensuring that the allocated tasks are being completed Current Known Risk Office staff are too busy</p> <p>Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q112 Process 5899 Proforma And Quote Chasing Chase outstanding Quotes and Proformas Current Known Risk Computer/network breakdown Not chased up.</p> <p>Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q113 Process 5901 Link Call Log Contacts To The CRM To link new calls to Contacts in the CRM Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q114 Process 5913 Check For Humanmed Orders In Logistics Mailbox Checking the logistics mailbox from within and the main inbox for outstanding Humanmed orders.</p> <p>NO LONGER REQUIRED HUMANEMD STOPPED Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q115 Process 5943 Check Cardea And Multiquote Checking the Cardea and Multiquote websites for outstanding orders or requests Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q116 Process 5949 Filling Credit Card Slips Check Square transactions for any anomalies or problems Current Known Risk wrong amounts charged and wrong customers</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q117 Process 7676 PDFing Of Invoices Viamed Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers</p> <p>NO LONGER REQUIRED AS DONE BY THE SYSTEM AUTOMATICALLY Current Known Risk Incorrect name given to Invoice when saving the PDF. customer gets incorrect invoice.</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>

210955Q118	<p>Process 7693 Collect Repair Filing From Warehouse Collect the filing form the warehouse Current Known Risk paperwork has been missed Current Likly 1 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q119	<p>Process 7699 Shred Sensitive Paperwork In JL Office Shredding of sensitive information Current Known Risk Broken shredder Current Likly 1 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q120	<p>Process 7712 Review Inward Payments Review the payments received to ensure proformas can be shipped Current Known Risk Computer network breakdown Current Likly 3 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q121	<p>Process 7735 Ensure SOR's Are Followed Up Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and the item(s) is returned as appropriate Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q122	<p>Process 7752 SRS Folder Ensure all outstanding repairs are being dealt with Current Known Risk repairs get stuck in the system Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q123	<p>Process 7758 Check For GHX Orders Check the emails for orders from GHX Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q124	<p>Process 7783 PDF VST Invoices And Purchase Orders Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers NOW DONE AUTOMATICALLY Current Known Risk Incorrect name given to Invoice when saving the PDF. customer gets incorrect invoice. Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q125	<p>Process 7795 Answering UK Web Questions Answering any questions that are asked via the website from within Intrastats Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q126	<p>Process 5859 Review Un-shipped Parcels audit and snap shot - this is an audit of a part of goods out, listing of the parcels that are sat waiting on a customer response Current Known Risk Customer forgets to come back to us and parcels stay ready for shipping. As the package is already pick pack and ready to leave the building all computer</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required No Action

traces will show as shipped.
Current Likly 2 Current Frequency 1

210955Q127	ProcessProcess 6954 Back Orders Review - By Customer To check the back orders in the tray in goods out and check the active list back orders has been reviewed Current Known Risk goods not shipped in a timely manner Current Likly 1 Current Frequency 1	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q128	ProcessProcess 7748 Check Repair Orders Check the orders against the customer paperwork, that we have generated, for the repair we have received in. Current Known Risk That details will be incorrect and it will affect the customer. That mistakes may be missed. Current Likly 2 Current Frequency 2	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q129	ProcessProcess 7749 Check Repair Quotes Check the quotes that we send out for the repairs we have received in. Current Known Risk That mistakes may be missed. That details will be incorrect and it will affect the customer. Current Likly 2 Current Frequency 2	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q130	ProcessProcess 7826 Goods In Processes To Receive Goods from Suppliers Current Known Risk incorrectly booked in not booked in Current Likly 2 Current Frequency 2	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q131	ProcessProcess 7821 Controlled Waste Description And Transfer The renewal of our waste transfer agreement with our waste disposal companies Current Known Risk That we cannot get rid of waste or we have a supplier that takes waste but does not dispose of it in the correct legal manor. Current Likly 1 Current Frequency 2	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q132	ProcessProcess 7820 North Yorkshire Council Waste Tranfer The renewal of our waste transfer agreement with North Yorkshire County Cououncil Current Known Risk That we cannot get rid of waste or we have a supplier that takes waste but does not dispose of it in the correct legal manor. Current Likly 1 Current Frequency 2	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q133	ProcessProcess 7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise Current Known Risk Issues could be missed Current Likly 3 Current Frequency 1	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q134	ProcessProcess 7842 Review VIAMED Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised Current Known Risk That an issue or report might be missed. That a Negative feedback form Products might not be reviewed Current Likly 3 Current Frequency 1	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q135	ProcessProcess 7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised Current Known Risk things are not followed up in a timely manner or are missed Current Likly 3 Current Frequency 1	Does Update Affect? <input type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required:	Notes On Risk / Benefits statement required No Action

No Action Required

210955Q136	Process 7840 Review VST Feedback - Customer Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised Current Known Risk That an issue or report might be missed. That a Negative feedback form Products might not be reviewed Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q137	Process 7839 Review VIAMED Feedback - Customer Complaints To Review Viamed Customer Complaints Current Known Risk Rolling Issue No Risk Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q138	Process 7838 Review VIAMED Feedback - Customer Feedback Negative Review Customer Feedback Negative Current Known Risk Rolling Issues No risk to process Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q139	Process 7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products In order to sell in the USA / Canada Markets products need to be registered with the FDA. Current Known Risk Its harder to initially get on teh register than maintaining it. Inability to sell products in North America Current Likly 1 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q140	Process 7831 Intrastats Debtors And Creditor Figures Intrastats Debtors And Creditor Figures Fill in the figure in Enter Overview details from Operas and bank. Current Known Risk Not filled in often enough Not filled in correctly Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q141	Process 7671 Humanmed Non Conformances Humanmed Non Conformances Current Known Risk non conformations not logged. Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required
210955Q142	Process 7846 ISO System Management Review Viamed To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13 Current Known Risk Failure to do may cause major non conformites in QMS System Current Likly 1 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q143	Process 7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards Current Known Risk No risks Rolling issue to perform task Current Likly 1 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action

<p>210955Q144 Process 7849</p> <p>Review Product Failures New Codes Review the Customer Returns and Review Product Failures New Codes Current Known Risk Product failures / returns do not get reviewed and a new Risk may occur Current Likly 1 Current Frequency 3</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q145 Process 7871</p> <p>Review Exclusion From Viamed 13485:2016 And VST 9001:2015 To review the Exclusions / boundaries to ISO 13485:2016 for Viamed Current Known Risk Something is missed. Current Likly 1 Current Frequency 3</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q146 Process 7837</p> <p>Review External Parties Influencing The QMS VST / Viamed To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks Current Known Risk External party has un-reviewed expectations Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q147 Process 7741</p> <p>Review Ethical Policy Review the current Ethical Policy in intrastats Current Known Risk That something is missed that we would like to include Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q148 Process 7713</p> <p>Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff, Current Known Risk That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q149 Process 7070</p> <p>Management Review To discuss any problems, to assess work load and staffing. To review issues. Current Known Risk Meetings not carried out regularly. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q150 Process 6931</p> <p>Customer Complaints Review the Customer Complaints Heading Current Known Risk things are not followed up in a timely manner or are missed Current Likly 1 Current Frequency 3</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q151 Process 7091</p> <p>Calibration Index To ensure that all equipment that requires calibration is done. In the correct timescale and manor. Make sure all equipment has a date of calibration on it Current Known Risk That equipment we use to may not be calibrated when we need it. Or the date may not be attached. Current Likly 1 Current Frequency 2</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q152 Process 7834</p> <p>Financial Review The review the Financial requirements Current Known Risk Non Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action</p>

210955Q153	<p>Process 5877 Review Company Data To review the numbers of various departments. Showing increasing / reducing staff requirements Check Audit Roles Titles and Processes in Employee Roles and Titles. Check the Page for Red Crosses and potentially missing objectives Current Known Risk incorrect staff levels Current Likly 3 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q154	<p>Process 7874 Review For Latest Version Med Dev 2.12. To Ensure we have the latest version of Med Dev 2.12. and update management if its been updated Current Known Risk Using out of date Med Dev Current Likly 1 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q155	<p>Process 7876 Maintain Update Of ISO Route Maps To review Route map VIAMED 13485:2016 and VST 9001:2015 See if a new Summary sheet needs producing, print new PDF, and upload on top of the old summary Current Known Risk Summary sheet gets out of date. Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q156	<p>Process 7878 Review Possible Upcoming Regulation Changes Review possible legal / regulator changes that might affect Viamed / VST Current Known Risk Legal / Regulatory changes stop us being able to carry out our processes as per QMS Current Likly 1 Current Frequency 3</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q157	<p>Process 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading. Current Known Risk Supplier certificates go out of date, or they lose ISO standards and we're unaware Current Likly 1 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q158	<p>Process 7071 Post Market Surveillance 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. Current Known Risk Loss of certifications Unforeseen product risks. Current Likly 1 Current Frequency 3</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q159	<p>Process 7199 Non Conformities Review Viamed 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. Current Known Risk Non conformances go unfixed Current Likly 2 Current Frequency 2</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q160	<p>Process 7833 Importance Of Effective Quality Management To Remind Staff of the Importance of the ISO systems and they should be following the procedures Current Known Risk people may become careless Current Likly 2 Current Frequency 1</p>	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement required No Action
210955Q161	<p>Process 6829 Supplier Review - Outstanding orders Orders that have not been supplied in the time scale provided.</p>	Does Update <input type="button" value="No"/>	Risk Frequency due to Update 2.Remote	Notes On Risk / Benefits statement required

<p>Current Known Risk That good will be delayed and therefore not available to customers. Current Likly 2 Current Frequency 2</p>	<p>Affect? No</p>	<p>Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>No Action
</p>
<p>210955Q162 ProcessProcess 6832 Supplier Review Future orders Orders that will be placed in the future. Current Known Risk That we will not place the correct orders and the right time. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q163 ProcessProcess 5881 Training Records Review Keep Staff Training records upto date See if any records need updating, also see if any records need signing off Current Known Risk Keep enough trained staff to perform our tasks Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q164 ProcessProcess 7847 Health And Safety Review Perform HSE Risk Assessment, Re issue Message of the Day or send company issue with regard to Employees being aware of HSE documentation / policy. and Location of Fire Exits and First Aid Kits. Send new Issue to Projects Asking if New HSE implications have arisen from new products. Review Online the Local Community Risk Register. Check the Viamed Overall Risk Analysis Program Document in the Index to check its still current. Check the health and safety signage Current Known Risk HSE Risks to Staff and business Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q165 ProcessProcess 7793 Team Review Meeting Duplicate Issue needs process removing see processid 7750 Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required</p>
<p>210955Q166 ProcessProcess 5887 Review ISO/EN Documents To Keep Products and Services up-to date with current regulations and standards Current Known Risk Shipping products and or services with below regulations and or standards Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q167 ProcessProcess 7753 Management Meeting Warehouse To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse. Current Known Risk Meetings not carried out regularly. Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q168 ProcessProcess 6851 Review Accident Book To look through the accident book and make sure there were no breaches of Health and Safety that were not reported. Current Known Risk That additions to the accident book have not been reported when serious. Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q169 ProcessProcess 7877 Disaster Planning</p>	<p>Does Update</p>	<p>Risk Frequency due to Update</p>	<p>Notes On Risk / Benefits statement required</p>

<p>To Plan for disaster Current Known Risk Total failure Current Likly 1 Current Frequency 3</p>	<p>Affect? No</p>	<p>3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>No Action
</p>
<p>210955Q170 ProcessProcess 8014 Review VIAMED Product Feedback Positive Review VIAMED Product Feedback Positive Current Known Risk Issues could be missed Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q171 ProcessProcess 8016 Review VIAMED Customer Feedback Positive Review Positive Customer Feedback Current Known Risk Issues could be missed Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q172 ProcessProcess 8019 Audit 04 Accounts And Finance VST Carry out Audit 04 Accounts for VST</p> <p>Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.</p> <p>If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such. Current Known Risk That something may impede the Audit, so it cannot be carried out fully. Current Likly 1 Current Frequency 2</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q173 ProcessProcess 8025 Check We Do Not Require A EU European Representatives Review the below statement and make sure it is still valid and correct. `Viamed Group of companies does not involve the large-scale use of special category or criminal offence data. We also only occasionally process low risk data of individuals in the EU. We do not need to appoint a EU European representatives.`</p> <p>With this in mind we have reasoned we are not required to appoint any EU European representatives in EU member states. Current Known Risk that we may miss something or find we have made a wrong decision Current Likly 1 Current Frequency 3</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q174 ProcessProcess 8026 Automotive Competitor Price Review To review competitor automotive prices</p> <p>Current Known Risk That we may miss a event that has caused a large increase or decrease in competitor prices. Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q175 ProcessProcess 7996 Verification Repairs Older Repairs Verification Repairs Older Repairs Find all repairs older than 60 Days. review why not been invoice / completed.</p> <p>Current Known Risk a repair is missed or not chased Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q176 ProcessProcess 8028 Viamed Shopify Sales Report Export Export the Viamed Shopify Sales transaction Report Current Known Risk report missed Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement required No Action
</p>
<p>210955Q177 ProcessProcess 8030 Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to</p>	<p>Notes On Risk / Benefits statement required</p>

Current Known Risk We over pay for products or services
Current Likly 1 Current Frequency 2

Update
1.Negligible ▾
Action Required:
No Action Required

No Action

210955Q178 ProcessProcess 7919
Send Debtors Overview To Derek
send a report to the managing director of what is happening with the debtors from the last month, include problems and payments due.

Can add to issue and redirect
Current Known Risk report not done
Current Likly 1 Current Frequency 1

Does Update Affect? No ▾
Risk Frequency due to Update 1.Improbable ▾
Risk Likly Due to Update 1.Negligible ▾
Action Required:
No Action Required

Notes On Risk / Benefits statement required
No Action

210955Q179 ProcessProcess 8084
VST Accounts On Stop
Accounts placed on stop as they owe money. To prevent orders being dispatched. Current Known Risk accounts being on stop when they have paid and preventing orders, that should be sent, from being shipped.
Payments coming in and them not being picked up in a timely manner.
Current Likly 2 Current Frequency 1

Does Update Affect? No ▾
Risk Frequency due to Update 1.Improbable ▾
Risk Likly Due to Update 2.Minor ▾
Action Required:
No Action Required

Notes On Risk / Benefits statement required
No Action

210955Q180 ProcessProcess 8085
Stock Figure - Correct Xero To Intrastats
To correct the stock in the accounts package so it matches what we have in the building and on Intrastats. So the figures are correct and we can get a better idea of where we are with finances
Current Known Risk That the figure is incorrect
The journal in xero is incorrect
Current Likly 1 Current Frequency 1

Does Update Affect? No ▾
Risk Frequency due to Update 1.Improbable ▾
Risk Likly Due to Update 1.Negligible ▾
Action Required:
No Action Required

Notes On Risk / Benefits statement required
No Action

210955Q181 ProcessProcess 8089
Review Any Outstanding QC 21 Forms To Sign Off
Review Any Outstanding QC 21 Forms. If completed, sign it off.
Review it to make sure all parts are completed satisfactorily
Current Known Risk Forms started might be missed, left un completed
Current Likly 1 Current Frequency 3

Does Update Affect? No ▾
Risk Frequency due to Update 3.Occasional ▾
Risk Likly Due to Update 1.Negligible ▾
Action Required:
No Action Required

Notes On Risk / Benefits statement required
There is a risk of an uncom form being missed. This proc is here to reduce the likeli of this ever happening.
N Action

210955Q182 Does Generic CE File Attached to All Technical file #2
Of type 5 require any Notificaiions and/or Risk assesment updates due to this update

Does Update Affect? No ▾
Risk Frequency due to Update 1.Improbable ▾
Risk Likly Due to Update 1.Negligible ▾
Action Required:
No Action Required

Notes On Risk / Benefits statement required

210955Q183 Final Notes

Fixed Title from saying Viamed - no actual document updated so, no risk to iso system

SAVE FORM Only saves your progress in filling in above Questions - No feed back to pressing save form button
Once Form Complete Print Page to PDF (Landscape mode preferable), go back to document upload page and upload to risk assesment button