## **Document VM3COP60.04 Viamed Disaster Planning Business Continuity Plan Reports Revision ID72870**

Completed	Upload Document Name: Risk Assesment For Updating Document ID72870 by Derek Lamb 22 Nov 2024 Risk Assesment				
	user details, and dates on the document				
Risk	VM3COP60.04 Viamed Disaster Planning Business Continuity Plan Reports Revision  Question	ID72870 Does Update Affect	Is linked to the Follow Risk on Update	ving Standards and processes  Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q0	Does this Update warrant updating Any External Parties due to any <b>Terms and Conditional Agreements</b> E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does O Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q1	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 V	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q2	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 Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q3	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 Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q4	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; 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.	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q5	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	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue

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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

72870Q6	Viamed Ltd ISO13485:2016 Section:
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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.

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No Action Required

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Viamed Ltd ISO13485:2016 Section: 8.2.5 Monitoring and measurement of processe

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.

Viamed Ltd ISO13485:2016 Section: 8.4 72870Q8

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:
- 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).

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72870Q9 VST Ltd ISO9001:2015 Section: 6.2.1

The organization shall establish quality objectives at relevant functions, levels and processes

needed for the quality management system.

- The quality objectives shall:
  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. The organization shall maintain documented information on the quality objectives

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72870O10 VST Ltd ISO9001:2015 Section: 8.5.5

Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services

In determining the extent of post-delivery activities that are required, the organization shall consider:

- 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.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such

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72870Q12	VST Ltd ISO9001:2015 Section: 9.1.1 General The organization shall determine: 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. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results.  VST Ltd ISO9001:2015 Section: 9.1.2 Customer satisfaction 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.  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.	Does Update Affect?  No   Does Update Affect?  No   No   No   No   No   No   No   No	to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required  Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required  Notes On Risk / Benefits statement if required	Further Action Required on Issue  Further Action Required on Issue
72870Q13	VST Ltd ISO9001:2015 Section: 9.1.3 Analysis and evaluation The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: 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. NOTE Methods to analyse data can include statistical techniques.	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q14	VST Ltd ISO9001:2015 Section: 9.2.1  The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained.	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q15	VST Ltd ISO9001:2015 Section: 9.2.2  The organization shall: 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.  NOTE See ISO 19011 for guidance.	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q16	VST Ltd ISO9001:2015 Section: 9.3.1 General 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.	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q17	VST Ltd ISO9001:2015 Section: 9.3.2  Management review inputs 9.3.2 Management review inputs The management review shall be planned and carried out taking into consideration: 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: 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;	Does Update Affect? No •	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

22/11/2024, 10:34  $vmserver 10. the vault.me.uk/intranet/databases/iso\_documents/risk\_asses\_docid.php?zz=1\&A=\&vui=2\&use...$ e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement. 72870Q18 Process55
Business Continuity Plan Further Action Required on Risk Frequecy due Notes On Risk / Benefits statement if Does required

	Business Continuity Plan	Affect?	1.Improbable V Risk Likly Due to Update 1.Negligible V Action Required: No Action Required		<u>a</u>
72870Q19	<sup>Q</sup> .Process22 Company Policys Ensure the company policys are still current and upto date	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q20	Qprocess23 Company Objectives Ensure the company Objects are still current and upto date	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q21	<sup>Q</sup> 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?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q22	© Process7834 Financial Review The review the Financial requirements	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q23	© 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 Freqency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q24	Q-Process26 Company Resources Overview of the Company using various data Reporting Screens	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q25	Q-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 Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q26	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?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q27	Q-Process7070 Management Review To discuss any problems, to assess work load and staffing. To review issues.	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q28	©Process5887 Review ISO/EN Documents To Keep Products and Services up-to date with current regulations and standards	Does Update Affect?	Risk Freqency due to Update  2.Remote  Risk Likly Due to Update  2.Minor  Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue

No Action Required

72870Q29	QProcess5889 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	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  4.Critical  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q30	QProcess6866 Internal Process Verification Complete Systems Review Review the Internal Process and Verification's are suitable for the current standards PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q31	© Process7071 Post Market Surveillance The process by which re view and risk assess all product files, check that no Product / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.	Does Update S Affect? No 🕶	Risk Freqency due to Update 3.0ccasional  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q32	QProcess7093 BSI Audits Calander Review of outstanding Audits	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q33	© Process7172 CE Technical Files Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q34	QProcess7138  Non Conformance Issues Any New QC21 Forms  To review any new QC 21 Forms  Check existing forms for corrective actions and effectivness	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q35	© Process 7808 Ensure All Invoice Correctly Tagged To find and Tag any sales that are removed from commissions, as they are break ever products for relationships purposes	Does Update a Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q36	©Process7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems.	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q37	© Process7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats.  Process no longer required with end of Opera	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q38	©Process57 Temporary Stock Notices To Review Memos on Stock references tagged as Temporary	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q39	© Process5854 Stock FAQ Admin List To update and maintain the Stock FAQ list	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

72870Q40	© Process6871 ISO14001 Environmental management systems Not yet Applied Rolling Issue to see if we should apply this standard in the future	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q41	© Process7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q42	© Process28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q43	© Process7877 Disaster Planning To Plan for disaster	Does Update Affect?	Risk Freqency due to Update 3.Occasional  Risk Likly Due to Update 1.Negligible Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q44	QProcess7879 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.	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q45	© 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	Does Update Affect? No •	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q46	^Process7878 Review Possible Upcoming Regulation Changes Review possible legal / regulator changes that might affect Viamed / VST	Does Update Affect?	Risk Freqency due to Update 3.0ccasional  Risk Likly Due to Update 1.Negligible Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q47	OProcess7885 Audit 04 Accounts and Finance Viamed Carry out Audit 04 Accounts for Viamed	Does Update Affect? No 🗸	Risk Freqency due to Update 2.Remote  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q48	<sup>Q</sup> 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	Does Update Affect? No •	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q49	Nerocess7888 Review Processes Linked To VOPs And Audits Ensure All Sub Processes are linked to a VOP and an Audit.	Does Update Affect? No •	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
72870Q50	QProcess7965 VST Feedback Enter Feedback from VST customer or Suppliers in the the Feedback headers Both Positive and Negative feedback to be logged	Does Update Affect?	Risk Freqency due to Update  2.Remote  Risk Likly Due to Update  2.Minor  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue	

72870Q51	© 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.	Does Update Affect? No •	Risk Freqency due to Update 2.Remote  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q52	©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	Does Update Affect? No •	Risk Freqency due to Update 2.Remote  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q53	Osprocess7972  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	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q54	QProcess7973 VST Product Performance - Customers To produce Product performance report showing 2 years of returns. Which we can use to send to customers.	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q55	© Process7974 VST Product Performance - Suppliers To produce Product performance report for Suppliers PMS Files	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q56	© Process7977 Review The Agenda For The Management Review / Board Meeting Prior To The Annual Meeting To review the Agenda of the Management review. Make sure no headers are missed that should be being discussed.  Make sure Objectives are appropriate and effective.	Does Update Affect? No 🗸	Risk Freqency due to Update 2.Remote  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required The addition of this task is aimed at reducing the risk of missing a header. If a header is missed the risk would be to miss discussing something important.	Further Action Required on Issue
72870Q57	<sup>Q</sup> Process7978  Regulatory Requirements and Review of QC21 form template To Regulatory Requirements and a Review of QC21 form template. To ensure they are up to date to the current standards review Qc 21 Form to ensure it is still appropriate and valid	Does Update Affect?	Risk Freqency due to Update 3.0ccasional  Risk Likly Due to Update 1.Negligible Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q58	<sup>Q</sup> Process7981 Review Process Updates For Risk To Systems To review monthly any changes, to any processes, for risks to ISO systems.	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q59	NProcess8012 VAT Return Viamed Properties VAT return is submitted to the HMRC through accounts software after the end of the quarter. The information for this is taken from the accounts package with some information from Intrastats	Does Update Affect?	Risk Freqency due to Update 2.Remote  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q60	QProcess7045 Design and Development 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 assessment Carry out the Technical File PMS Form for Each OBL and Viamed Product Using procedure VM3COP27.11 See VM3COP18		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q61	QProcess7849 Review Product Failures New Codes Review the Customer Returns and Review Product Failures New Codes	Does Update Affect?	Risk Frequency due to Update 3.Occasional  Risk Likly Due to Update 1.Negligible Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue

			No Action Required		
72870Q62	<sup>Q</sup> -Process7830 Review Q.A. Failures Report To review the Quantities of Failed product per Stock reference Passing through the Q.A. system	Does Update Affect? No 🗸	Risk Freqency due to Update  [1.Improbable > Risk Likly Due to Update 3.Serious > Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q63	© Process8014 Review VIAMED Product Feedback Positive Review VIAMED Product Feedback Positive	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q64	© Process8015 Review VST Product Feedback Positive Review VST Product Feedback Positive	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q65	©Process8016 Review VIAMED Customer Feedback Positive Review Positive Customer Feedback	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q66	QProcess8017 Review VST Customer Feedback Positive Review VST Customer Feedback Positive	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q67	CProcess8018 Wednesday Meeting Rolling Issue for Notes During the Weekly Meeting To discuss any problems, to assess work load and staffing. To review issues.	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required Hands on Learning from experienced staff	Further Action Required on Issue
72870Q68	©Process8019 Audit 04 Accounts And Finance VST Carry out Audit 04 Accounts for VST	Does Update Affect?	Risk Freqency due to Update  2.Remote  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q69	©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	Does Update Affect?	Risk Freqency due to Update  [1.Improbable > Risk Likly Due to Update [1.Negligible > Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q70	©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	Does Update Affect?	Risk Freqency due to Update  [1.Improbable > Risk Likly Due to Update [1.Negligible > Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q71	<sup>Q</sup> Process8073 Quarterly Stock Meeting Due Quarterly Stock Meeting Due - Full Stock Meeting Due	Does Update Affect?		Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q72	OProcessProcess 7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file.	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to	Notes On Risk / Benefits statement if required	Further Action Required on Issue

22/11/2024, 10:34 vmserver10.thevault.me.uk/intranet/databases/iso\_documents/risk\_asses\_docid.php?zz=1&A=&vui=2&use... 72870Q83 QProcessProcess 7709 Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Update to Update required Delivered not Invoiced Ensure invoices are generated for shipped orders Affect? 2.Remote Current Known Risk Computer/network breakdown delivery is missed and remains un invoiced. No 🕶 Risk Likly Due to Update Current Likly 2 Current Frequency 2 2.Minor Action Required: No Action Required 72870Q84 QProcessProcess 7953 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Update to Update Vandagraph Delivery Notifications required Issue 1.Improbable ✔ To Send Vandagraph Delivery notifications Affect? Current Known Risk task not carried out No 🕶 Risk Likly Due to Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 72870Q85 ProcessProcess 7691 Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Does Update to Update Ship Sale Or Returns required Issue Affect? Review the sale or return shelf and ship those items. 1.Improbable 🗸 Current Known Risk Goods will be missed No 🕶 Risk Likly Due to Current Likly 2 Current Frequency 1 Update 2.Minor Action Required: No Action Required 72870Q86 AProcessProcess 7690 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does required Update to Update Issue Ship Repairs Review the Repairs completed shelf and ship those items that are ready for return to Affect? 1.Improbable the customer. No 🕶 Risk Likly Due to Current Known Risk That a repair will be missed Update Current Likly 2 Current Frequency 1 2.Mino Action Required: No Action Required 72870Q87 OprocessProcess 7686 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does Thorough Checking Of Awaiting Action Tray - Priority 8s Update to Update required Issue Check that outstanding orders with unresolved issues are being followed up and Affect? 1.Improbable ➤ Risk Likly Due to addressed No 🗸 Current Known Risk Computer/network breakdown Update 2.Mino Current Likly 2 Current Frequency 1 Action Required: No Action Required 72870O88 Sprocess Process 7685 Risk Fregency due Notes On Risk / Benefits statement if Does Further Action Required on required Repairs Ready For Invoice Update to Update Issue 1.Improbable 🗸 Affect? Process Invoice for completed repairs. Risk Likly Due to Current Known Risk repair has errors on it No 🗸 Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 72870Q89 QProcessProcess 7684 Does Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Update to Update Repairs Ready For Quote Issue 1.Improbable >
Risk Likly Due to Process Repairs Ready For Quote Affect? Current Known Risk If process does not get performed, we likly to loose customers, No ✔ get complaints over not responding to customers returned goods Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 72870Q90 ProcessProcess 7683 Does Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Update to Update required Issue Check Stock For Proforma Affect? 1.Improbable To check that we have stock in for customer proformas. Or review if any stock needs to be ordered No ✔ Risk Likly Due to Current Known Risk That a customer is told we have stock and then we are unable to Update 2.Mino Current Likly 2 Current Frequency 1 Action Required: No Action Required 72870Q91 QProcessProcess 7678 Risk Fregency due Does Notes On Risk / Benefits statement if Further Action Required on required Check Catalog 360 Circle For Quotes And Orders Update to Update 1.Improbable >
Risk Likly Due to Checking the Catalog 360 Circle website for outstanding orders or requests Affect? No 🕶 SYSTEM NO LONGER USED Update Current Known Risk Computer/network breakdown 2.Mino Action Required: Current Likly 2 Current Frequency 1 No Action Required Does Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Check Repairs Ready For Invoice List Update to Update required Review the repairs ready For invoice List in intrastats Affect? 1.Improbable Risk Likly Due to Current Known Risk That repairs will be missed. No 🗸 Current Likly 2 Current Frequency 1 Update 2 Mino Action Required: No Action Required 72870Q93 ProcessProcess 7673 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on to Update Check Expiry Dated Stock Update required To check that all the stock on the selves are within their use by dates Affect? 2 Remote Risk Likly Due to Current Known Risk Stock being dispatched that is pasts its date. No ✓ Current Likly 1 Current Frequency 2 Update 1.Negligible Action Required: No Action Required

22/11/2024, 10:34 vmserver10.thevault.me.uk/intranet/databases/iso\_documents/risk\_asses\_docid.php?zz=1&A=&vui=2&use... 72870Q94 OProcessProcess 7670 Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Update to Update required Issue Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems. Affect? 1.Improbable 🗸 Current Known Risk That there are duplicate orders o the system due to errors. No 🕶 Risk Likly Due to Current Likly 3 Current Frequency 1 Update 3.Serious Action Required: No Action Required 72870Q95 QProcessProcess 6898 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on GHX Web Pricing Update to Update required Issue Affect? To review the GHX Web Pricing Risk Likly Due to 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 Update Current Likly 1 Current Frequency 2 1.Negligible Action Required: No Action Required 72870Q96 QProcessProcess 5871 Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Does Update to Update required Check Sale Or Returns Issue Affect? Review the Sale or Return list in intrastats. Ensure it is up to date. 1.Improbable 🗸 Current Known Risk That goods could be sent to a customer or goods returned but No 🕶 Risk Likly Due to Update the list is not updated 2.Minor Current Likly 2 Current Frequency 1 Action Required: No Action Required 72870Q97 QProcessProcess 5876 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does required E.Commerce Cardea And Multiquote Update to Update Issue To Collect E.Commerce Cardea And Multiquote Orders Affect? 1.Improbable Current Known Risk Orders go unnoticed No 🗸 Risk Likly Due to Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 72870Q98 OprocessProcess 5872 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does Update to Update required Check Sale Or Returns Export Issue Affect? 1.Improbable ➤ Review the Sale or Return list in intrastats. Ensure it is up to date. Risk Likly Due to Current Known Risk That goods could be sent to a customer or goods returned but No 🗸 the list is not updated Update 2.Mino Current Likly 2 Current Frequency 1 Action Required: No Action Required 72870099 Sprocess Process 11 Does Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Update to Update required Distribution Of Post Issue 1.Improbable ✔ Affect? Distibuting incoming post to correct person Current Known Risk Royal Mail fail to deliver post No 🗸 Risk Likly Due to Update Current Likly 3 Current Frequency 1 3.Serious Action Required: No Action Required 72870Q100 QProcessProcess 14 Does Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Update to Update Fax Paper Issue 1.Improbable >
Risk Likly Due to Affect? Ensuring that fax reports have been generated for both sent and received faxes and ensuring there is paper in the fax machine No ✔ Current Known Risk Phone lines go down Update The paper tray is empty 1.Negligible Current Likly 1 Current Frequency 1 Action Required: No Action Required 72870Q101 QProcessProcess 15 Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Does to Update required Update Issue Filing and Archiving Paperwork to be filed in the correct order Affect? 1.Improbable Current Known Risk Paperwork is filed incorrectly No 🕶 Risk Likly Due to Current Likly 1 Current Frequency 1 Update 1.Negligible Action Required: No Action Required 72870Q102 QProcessProcess 21 Risk Fregency due Does Notes On Risk / Benefits statement if Further Action Required on required Update to Update Office Sales Projects 1.Improbable >
Risk Likly Due to Ensuring office job list is being updated and completed Affect? Current Known Risk Office is short staffed or over worked No ✔ Current Likly 2 Current Frequency 1 Update 2.Mino Action Required: No Action Required 72870Q103 \ProcessProcess 36 Does Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Update to Update required **Emailing Of Invoices** Invoices are emailed to customers Affect? 1.Improbable Risk Likly Due to Current Known Risk Computer or network failure No 🗸 Current Likly 2 Current Frequency 1 Update 2 Mino Action Required: No Action Required 72870Q104 ProcessProcess 5875 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on to Update Check Paypal For Orders Update 1.Improbable >
Risk Likly Due to Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox Affect? No 🗸 Current Known Risk Computer/network breakdown Update 2.Mino Current Likly 2 Current Frequency 1 Action Required: No Action Required

22/11/2024, 10:34 vmserver10.thevault.me.uk/intranet/databases/iso\_documents/risk\_asses\_docid.php?zz=1&A=&vui=2&use... Risk Frequency due Notes On Risk / Benefits statement if 72870Q105 QProcessProcess 5882 Further Action Required on to Update Update required Issue Send Post To Humanmed 1.Improbable ✔ Humanedmed post is received, it needs to be forwarded to Humanmed UK Sales Affect? No 🕶 Risk Likly Due to Update HumanMed has Gone, tasks no longer required 4.Critical Current Known Risk Post is not sent Action Required: Current Likly 4 Current Frequency 1 No Action Required 72870Q106 QProcessProcess 5892 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Update to Update Checking EBay And Amazon For Orders And Messages required Issue Affect? Checking the eBay and Amazon accounts for orders that have not been emailed to Risk Likly Due to the main inbox and checking to see if there are messages or questions. No 🕶 Update Current Known Risk Computer/network breakdown 2.Mino Action Required: Current Likly 2 Current Frequency 2 No Action Required 72870Q107 QProcessProcess 5893 Risk Frequency due  $\;\;$  Notes On Risk / Benefits statement if Further Action Required on Does Update to Update required Answering Website Questions Issue Answering any questions that are asked via the website from within Intrastats Affect? 1.Improbable 🗸 No ✔ Risk Likly Due to PROCESS NO LONGER REQUIRED Web QUESTIONS NOW COME IN VIA Update 1.Negligible shopify, and Email Current Known Risk Computer/network breakdown Action Required: No Action Required Current Likly 1 Current Frequency 1 72870Q108 OprocessProcess 5894 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on required Checking Of Active List Update to Update Issue Affect? Check the Active Back orders ensure no orders get missed 1.Improbable ∨ Current Known Risk List is not reviewed and orders do not get shipped No 🗸 Risk Likly Due to Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 72870Q109 ProcessProcess 5895 Does Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Update Affect? required Completing Office Job List to Update Ensuring that the allocated tasks are being completed 1.Improbable > Current Known Risk Office staff are too busy No 🗸 Risk Likly Due to Current Likly 3 Current Frequency 1 Update 3.Serious Action Required: No Action Required 72870Q110 OprocessProcess 5899 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on required Proforma And Quote Chasing Update to Update Issue Chase outstanding Quotes and Proformas Affect? 1.Improbable > Current Known Risk Computer/network breakdown Risk Likly Due to No 🗸 Not chased up Update Current Likly 3 Current Frequency 1 3.Serious Action Required: No Action Required 72870Q111 OprocessProcess 5901 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Link Call Log Contacts To The CRM To link new calls to Contacts in the CRM Update Affect? to Update required 1.Improbable > Current Known Risk Computer/network breakdown No 🗸 Risk Likly Due to Current Likly 2 Current Frequency 1 Update 2.Mino Action Required: No Action Required 72870Q112 OprocessProcess 5913 Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Update Affect? Check For Humanmed Orders In Logistics Mailbox to Update required Issue Checking the logistics mailbox from within and the main inbox for outstanding 1.Improbable > Risk Likly Due to No 🗸 Update NO LONGER REQUIRED HUMANEMD STOPPED 2.Mino Current Known Risk Computer/network breakdown Action Required: Current Likly 2 Current Frequency 1 No Action Required 72870Q113 ProcessProcess 5943 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Check Cardea And Multiquote Checking the Cardea and Multiquote websites for outstanding orders or requests Update Affect? to Update required Issue 1.Improbable Risk Likly Due to Current Known Risk Computer/network breakdown No 🗸 Current Likly 2 Current Frequency 1 Update 2.Mino Action Required: No Action Required 72870Q114 OprocessProcess 5949 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Update Affect? Filling Credit Card Slips to Update required Issue Check Square transactions for any anomalies or problems 2.Remote Current Known Risk wrong amounts charged and wrong customers Risk Likly Due to No 🗸 Current Likly 2 Current Frequency 2 Undate 2.Mino Action Required: No Action Required 72870Q115 OprocessProcess 7676 Notes On Risk / Benefits statement if Risk Freqency due Further Action Required on PDFing Of Invoices Viamed Process of PDF ing Invoices into the system for easy of use in the future and the Update Affect? to Update required Issue 1.Improbable > Emailing of Invoices to customers No Risk Likly Due to Update NO LONGER REQUIRED AS DONE BY THE SYSTEM AUTOMATICALLY 2.Mino Current Known Risk Incorrect name given to Invoice when saving the PDF. Action Required: customer gets incorrect invoice. No Action Required Current Likly 2 Current Frequency 1

22/11/2024, 10:34 vmserver10.thevault.me.uk/intranet/databases/iso\_documents/risk\_asses\_docid.php?zz=1&A=&vui=2&use... 72870Q116 QProcessProcess 7693 Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Update to Update Collect Repair Filing From Warehouse required Issue 1.Improbable ✔ Collect the filing form the warehouse Affect? Current Known Risk paperwork has been missed No 🕶 Risk Likly Due to Current Likly 1 Current Frequency 1 Update 1.Negligible Action Required: No Action Required 72870Q117 QProcessProcess 7699 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Update to Update Shred Sensitive Paperwork In JL Office required Issue Shredding of sensitive information Affect? 1.Improbable 🗸 Current Known Risk Broken shredder No 🕶 Risk Likly Due to Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 72870Q118 QProcessProcess 7712 Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Does Update to Update required Review Inward Payments Issue Affect? Review the payments received to ensure proformas can be shipped 1.Improbable 🗸 Current Known Risk Computer network breakdown No 🕶 Risk Likly Due to Update Current Likly 3 Current Frequency 1 3.Serious Action Required: No Action Required 72870Q119 ProcessProcess 7735 Does Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on required Update to Update Issue Ensure SOR's Are Followed Up Ensure samples and Sale or Return items are followed up after 4 weeks for feedback Affect? 1.Improbable and the item(s) is returned as appropriate No 🕶 Risk Likly Due to Current Known Risk Computer/network breakdown Update Current Likly 2 Current Frequency 1 2.Mino Action Required: No Action Required 72870Q120 AProcessProcess 7752 Risk Freqency due Notes On Risk / Benefits statement if Does Further Action Required on Update to Update required SRS Folder Issue Affect? 1.Improbable ➤ Ensure all outstanding repairs are being dealt with Risk Likly Due to Current Known Risk repairs get stuck in the system No 🗸 Current Likly 2 Current Frequency 1 Update 2.Mino Action Required: No Action Required 72870Q121 ProcessProcess 7758 Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Does Check For GHX Orders Update to Update required Issue Affect? 1.Improbable Check the emails for orders from GHX Current Known Risk Computer/network breakdown No 🗸 Risk Likly Due to Update Current Likly 2 Current Frequency 1 2.Mino Action Required: No Action Required 72870Q122 QProcessProcess 7783 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does Update to Update PDF VST Invoices And Purchase Orders required Issue 1.Improbable >
Risk Likly Due to Process of PDF ing Invoices into the system for easy of use in the future and the Affect? Emailing of Invoices to customers No 🗸 Update NOW DONE AUTOMATICALLY 2.Mino Current Known Risk Incorrect name given to Invoice when saving the PDF. Action Required: customer gets incorrect invoice. No Action Required Current Likly 2 Current Frequency 1 72870Q123 QProcessProcess 7795 Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Answering UK Web Questions Update Affect? to Update required Issue Answering any questions that are asked via the website from within Intrastats 1.Improbable > Risk Likly Due to Current Known Risk Computer/network breakdown No 🗸 Current Likly 1 Current Frequency 1 Update 1.Negligible Action Required: No Action Required 72870Q124 ProcessProcess 5859 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Update Affect? Review Un-shipped Parcels to Update required Issue audit and snap shot - this is an audit of a part of goods out, listing of the parcels that 1.Improbable Risk Likly Due to are sat waiting on a customer response No 🗸 Current Known Risk Customer forgets to come back to us and parcels stay ready for Update shipping. 2.Mino As the package is already pick pack and ready to leave the building all computer Action Required: traces will show as shipped. No Action Required Current Likly 2 Current Frequency 1 72870Q125 CProcessProcess 6954 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Back Orders Review - By Customer Update to Update required 1.Improbable ➤ To check the back orders in the tray in goods out and check the active list back orders Affect? Risk Likly Due to has been reviewed No ✔ Current Known Risk goods not shipped in a timely manner Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 72870Q126 QProcessProcess 7748 Notes On Risk / Benefits statement if Does Risk Fregency due Further Action Required on required Update to Update Check Repair Orders Issue Affect? 2 Remote Check the orders against the customer paperwork, that we have generated, for the Risk Likly Due to repair we have received in. No 🗸 Current Known Risk That details will be incorrect and it will affect the customer. Update 2 Mino That mistakes may be missed. Current Likly 2 Current Frequency 2 Action Required: No Action Required

22/11/2024, 10:34 vmserver10.thevault.me.uk/intranet/databases/iso\_documents/risk\_asses\_docid.php?zz=1&A=&vui=2&use... 72870Q127 OprocessProcess 7749 Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Update to Update required Check Repair Quotes Check the quotes that we send out for the repairs we have received in. Affect? 2.Remote Current Known Risk That mistakes may be missed. That details will be incorrect and it will affect the customer. No 🕶 Risk Likly Due to Update Current Likly 2 Current Frequency 2 2.Minor Action Required: No Action Required 72870Q128 QProcessProcess 7826 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Update to Update required Goods In Processes Issue Affect? To Receive Goods from Suppliers Risk Likly Due to Current Known Risk incorrectly booked in No 🕶 Update not booked in Current Likly 2 Current Frequency 2 2.Mino Action Required: No Action Required 72870Q129 QProcessProcess 7821 Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on Does Update to Update Controlled Waste Description And Transfer required Issue Affect? The renewal of our waste transfer agreement with our waste disposal companies Risk Likly Due to Current Known Risk That we cannot get rid of waste or we have a supplier that takes No 🕶 waste but does not dispose of it in the correct legal manor. Update 1.Negligible Current Likly 1 Current Frequency 2 Action Required: No Action Required 72870Q130 CProcessProcess 7820 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does required North Yorkshire Council Waste Tranfer Update to Update Issue The renewal of our waste transfer agreement with North Yorkshire County Couoncil Affect? 2.Remote Risk Likly Due to Current Known Risk That we cannot get rid of waste or we have a supplier that takes No 🕶 Update waste but does not dispose of it in the correct legal manor. Current Likly 1 Current Frequency 2 1.Negligible Action Required: No Action Required 72870Q131 QProcessProcess 7843 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does Review VST Product Feedback Negative Update to Update required To review Negative feedback form Products Affect? 1.Improbable ➤ Risk Likly Due to see if Non Conformance or customer Complaints need to be raise No 🗸 Current Known Risk Issues could be missed Update Current Likly 3 Current Frequency 1 3.Serious Action Required: No Action Required 72870Q132 ProcessProcess 7842 Risk Fregency due Does Notes On Risk / Benefits statement if Further Action Required on Review VIAMED Product Feedback Negative Update to Update required Issue To review Negative feedback form Products Affect? 1.Improbable 🗸 see if Non Conformance or customer Complaints need to be raised No 🗸 Risk Likly Due to Current Known Risk That an issue or report might be missed. Update That a Negative feedback form Products might not be reviewed 3.Serious Current Likly 3 Current Frequency 1 Action Required: No Action Required 72870Q133 AProcessProcess 7841 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does Review VST Feedback - Customer Complaints Update to Update Issue 1.Improbable >
Risk Likly Due to To review Customer Complaints Affect? see if Non Conformance need to be raised No 🗸 Current Known Risk things are not followed up in a timely manner or are missed Update Current Likly 3 Current Frequency 1 3.Serious Action Required: No Action Required 72870Q134 ProcessProcess 7840 Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Does Review VST Feedback - Customer Feedback Negative Update to Update required Issue To review Negative feedback form Products Affect? 1.Improbable see if Non Conformance or customer Complaints need to be raised No 🕶 Risk Likly Due to Current Known Risk That an issue or report might be missed. That a Negative feedback form Products might not be reviewed 3.Serious Current Likly 3 Current Frequency 1 Action Required: No Action Required 72870Q135 \(\text{ProcessProcess}\) 7839 Risk Fregency due Notes On Risk / Benefits statement if Does Further Action Required on required Review VIAMED Feedback - Customer Complaints to Update 1.Improbable >
Risk Likly Due to To Review Viamed Customer Complaints Affect? Current Known Risk Rolling Issue No Risk No 🕶 Current Likly 3 Current Frequency 1 Update 3.Serious Action Required: No Action Required 72870Q136 CProcessProcess 7838 Does Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Review VIAMED Feedback - Customer Feedback Negative Update to Update required Review Customer Feedback Negative Affect? 1.Improbable Risk Likly Due to Current Known Risk Rolling Issues No risk to process No 🗸 Current Likly 3 Current Frequency 1 Update 3 Serious Action Required: No Action Required 72870Q137 OProcessProcess 7744 Does Risk Frequecy due Notes On Risk / Benefits statement if Further Action Required on to Update FDA Device Establishment Registration And Listing Update 1.Improbable >
Risk Likly Due to FDA registration and the CMDCAS products Affect? No 🗸 In order to sell in the USA / Canada Markets products need to be registered with the Update FDA. 1.Negligible Action Required: No Action Required Current Known Risk Its harder to initially get on teh register than maintaining it.

## 22/11/2024, 10:34 $vmserver 10. the vault.me.uk/intranet/databases/iso\_documents/risk\_asses\_docid.php?zz=1\&A=\&vui=2\&use...\\$ Inability to sell products in North America Current Likly 1 Current Frequency 1 $Risk\ Frequency\ due\quad \ Notes\ On\ Risk\ /\ Benefits\ statement\ if$ Further Action Required on Does Update Affect? to Update required Issue 1.Improbable ➤

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	Affect?	1.Improbable V Risk Likly Due to Update 3.Serious V Action Required: No Action Required		4
72870Q139 CProcessProcess 7671 Humanmed Non Conformances Humanmed Non Conformances Current Known Risk non conformations not logged. Current Likly 2 Current Frequency 2	Does Update Affect?	Risk Freqency due to Update 2.Remote  Risk Likly Due to Update 2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q140 ProcessProcess 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 Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q141 \(^\text{ProcessProcess}\) 72870Q141 \(^\text{ProcessProcess}\) 72870Q141 \(^\text{ProcessProcess}\) 708 \(^\text{Process}\) 708 \(^\text{ProcessProcess}\) 708 \(^Process	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q142 \(^\text{ProcessProcess}\) Product Failures New Codes 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	Does Update Affect? No 🗸	Risk Freqency due to Update 3.0ccasional  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q143 \(^\text{ProcessProcess}\) ProcessProcess 7871 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 1	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q144 QProcessProcess 7837 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	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q145 \( \text{ProcessProcess} 7741 \) 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	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q146 ProcessProcess 7713 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	Does Update Affect?	Risk Freqency due to Update  2.Remote  Risk Likly Due to Update  2.Minor  Action Required:  No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q147 \(^\text{ProcessProcess}\) ProcessProcess 7070  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	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q148 ProcessProcess 6931 Customer Complaints Review the Customer Complaints Heading	Does Update Affect?	Risk Freqency due to Update  3.0ccasional  Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

No Action Required

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72870Q159 \(^\)ProcessProcess 6829 Supplier Review - Outstanding orders Orders that have not been supplied in the time scale provided. Current Known Risk That good will be delayed and therefore not available to customers. Current Likly 2 Current Frequency 2	Does Update Affect? No 🕶	Risk Freqency due to Update  2.Remote  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q160 \(^\)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	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q161 AprocessProcess 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	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q162 \(^\text{ProcessProcess}\) 72870Q162 \(^\text{ProcessProcess}\) 72870Q162 \(^\text{ProcessProcess}\) 72870Q162 \(^\text{ProcessProcess}\) 72870 \(^Pr	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q163 A Process Process 7793 Team Review Meeting Duplicate Issue needs process removing see processid 7750 Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1	Does Update Affect? No •	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q164 \(^\text{ProcessProcess}\) Focuments  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	Does Update Affect?	Risk Freqency due to Update  2.Remote Pisk Likly Due to Update  2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q165 AProcessProcess 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	Does Update Affect?	Risk Frequency due to Update  1.Improbable  Risk Likly Due to Update 3.Serious  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q166 AProcessProcess 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	Does Update Affect?	Risk Freqency due to Update  2.Remote  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q167 <sup>©</sup> -ProcessProcess 7877 Disaster Planning To Plan for disaster Current Known Risk Total failure Current Likly 1 Current Frequency 3	Does Update Affect?	Risk Freqency due to Update  3.0ccasional  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
72870Q168 © 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	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	AProcessProcess 8016 Review VIAMED Customer Feedback Positive Review Positive Customer Feedback Current Known Risk Issues could be missed Current Likly 1 Current Frequency 1	Does Update Affect? No 🕶	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required or Issue
	QProcessProcess 8019 Audit 04 Accounts And Finance VST Carry out Audit 04 Accounts for VST Current Known Risk That something may impede the Audit, so it cannot be carried out fully. Current Likly 1 Current Frequency 2	Does Update Affect? No 🕶		Notes On Risk / Benefits statement if required	Further Action Required or Issue
	**Opprocess**Process** 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.  *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**		Risk Freqency due to Update 3.Occasional  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required or Issue
	OrcessProcess 8026 Automotive Competitor Price Review To review competitor automotive prices  Current Known Risk That we may miss a event that has caused a large increase or decease in competitor prices.  Current Likly 1 Current Frequency 1	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required or Issue
	Q-ProcessProcess 7996 Verification Repairs Older Repairs Verification Repairs Older Repairs Verification Repairs Older Repairs Find all repairs older than 60 Days. review why not been invoice / completed.  Current Known Risk a repair is missed or not chased Current Likly 1 Current Frequency 1	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required or Issue
-	AProcessProcess 8028 Viamed Shopify Sales Report Export Export the Viamed Shopify Sales transaction Report Current Known Risk report missed Current Likly 1 Current Frequency 1	Does Update Affect? No 🗸	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required or Issue
·	QProcessProcess 8030 Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier Current Known Risk We over pay for products or services Current Likly 1 Current Frequency 2	Does Update Affect?	Risk Freqency due to Update  2.Remote  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required or Issue
	Or Process Process 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 🗸		Notes On Risk / Benefits statement if required	Further Action Required or Issue
	Does Generic CE File Attached to All Technical file #2 Of type 5 require any Notificaions and/or Risk assesment updates due to this update	Does Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible	Notes On Risk / Benefits statement if required	Further Action Required or Issue
			Action Required: No Action Required		<i>h</i>

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 prefereable), go back to document upload page and upload to risk assessment button