

Document VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews and Analysis Data Revision ID53797

Suggested Upload Document Name: **Risk Assesment For Updating Document ID53797**

Completed by Derek Lamb 17 Nov 2021

Reason for Risk Assesment

Feedback process was not fully effective as PMS procedure was not seenRisk Assesment For Updating Document ID53797 to be updated according applicable regulatory requirements for the CE products which are still in service.

Document VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews and Analysis Data Revision ID53797 Is linked to the Following Standards and processes

Risk Assesment ID53797	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q0	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 if required	Further Action Required on Issue
53797Q1	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;	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 if required	Further Action Required on Issue

e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).

53797Q2	<p>Viamed Ltd ISO13485:2016 Section: 5.6.1</p> <p>General</p> <p>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.</p> <p>Records from management reviews shall be maintained</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q3	<p>Viamed Ltd ISO13485:2016 Section: 5.6.2 Review input</p> <p>General</p> <p>The input to management review shall include, but is not limited to, information arising from:</p> <ul style="list-style-type: none">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.	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q4	<p>Viamed Ltd ISO13485:2016 Section: 8.1</p> <p>General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:</p> <ul style="list-style-type: none">a) demonstrate conformity of product;b) ensure conformity of the quality management system;c) maintain the effectiveness of the quality management system. <p>This shall include determination of appropriate methods, including statistical</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

techniques, and the extent of their use.

53797Q5	<p>Viamed Ltd ISO13485:2016 Section: 8.2.1</p> <p>Feedback</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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>	<p>Does Update Affect? <input type="button" value="Yes"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likely Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: Needs Setting</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Requirements of MDR Art. 120 Added</p> <p>no negative effect to the system</p>	<p>Further Action Required on Issue</p> <p>241893</p>
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53797Q6	<p>Viamed Ltd ISO13485:2016 Section: 8.2.4</p> <p>Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p> <p>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.</p> <p>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</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likely Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
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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.

53797Q7	<p>Viamed Ltd ISO13485:2016 Section: 8.2.5</p> <p>Monitoring and measurement of processes</p> <p>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>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likely Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q8	<p>Viamed Ltd ISO13485:2016 Section: 8.4</p> <p>Analysis of data</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> 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. <p>If the analysis of data shows that the quality management system is not suitable, adequate or effective,</p>	<p>Does Update Affect? <input type="button" value="No"/></p>	<p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likely Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

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).

53797Q9	<p>VST Ltd ISO9001:2015 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</p> <p><input type="button" value="1.Improbable"/> ▼</p> <p>Risk Likly Due to Update</p> <p><input type="button" value="1.Negligible"/> ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q10	<p>VST Ltd ISO9001:2015 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. 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</p> <p><input type="button" value="1.Improbable"/> ▼</p> <p>Risk Likly Due to Update</p> <p><input type="button" value="1.Negligible"/> ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q11	<p>VST Ltd ISO9001:2015 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	<p>Does Update Affect? <input type="button" value="No"/> ▼</p>	<p>Risk Frequency due to Update</p> <p><input type="button" value="1.Improbable"/> ▼</p> <p>Risk Likly Due to Update</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

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.

1.Negligible ▾
 Action
 Required:
 No Action
 Required

53797Q12	<p>VST Ltd ISO9001:2015 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? No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q13	<p>VST Ltd ISO9001:2015 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> <p>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> <p>NOTE Methods to analyse data can include statistical techniques.</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q14	<p>VST Ltd ISO9001:2015 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> <p>1) the organization's own requirements for its quality management system;</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

- 2) the requirements of this International Standard;
b) is effectively implemented and maintained.

Action
Required:
No Action
Required





53797Q15	VST Ltd ISO9001:2015 Section: 9.2.2	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 if required	Further Action Required on Issue
	<p>The organization shall:</p> <p>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;</p> <p>b) define the audit criteria and scope for each audit;</p> <p>c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;</p> <p>d) ensure that the results of the audits are reported to relevant management;</p> <p>e) take appropriate correction and corrective actions without undue delay;</p> <p>f) retain documented information as evidence of the implementation of the audit programme and the audit results.</p> <p>NOTE See ISO 19011 for guidance.</p>				
53797Q16	VST Ltd ISO9001:2015 Section: 9.3.1 General	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 if required	Further Action Required on Issue
	<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>				
53797Q17	VST Ltd ISO9001:2015 Section: 9.3.2 Management review inputs	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue
	<p>9.3.2 Management review inputs</p> <p>The management review shall be planned and carried out taking into consideration:</p> <p>a) the status of actions from previous management reviews;</p> <p>b) changes in external and internal issues that are relevant to the quality management system;</p>				

- 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;
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.





No Action
Required

53797Q18	<div> Process22 </div> <div>Company Policy</div> <div>Ensure the company policy is still current and up to date</div>	<div> <div>Does Update Affect?</div> <div>No</div> </div> <div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> </div> <div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> </div> <div> <div>Action Required:</div> <div>No Action Required</div> </div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>
53797Q19	<div> Process23 </div> <div>Company Objectives</div> <div>Ensure the company Objects are still current and up to date</div>	<div> <div>Does Update Affect?</div> <div>No</div> </div> <div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> </div> <div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> </div> <div> <div>Action Required:</div> <div>No Action Required</div> </div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>
53797Q20	<div> Process55 </div> <div>Business Continuity Plan</div> <div>Business Continuity Plan</div>	<div> <div>Does Update Affect?</div> <div>No</div> </div> <div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> </div> <div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> </div> <div> <div>Action Required:</div> <div></div> </div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>





No Action
Required

53797Q21	 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? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likly Due to Update <div>1.Negligible ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q22	 Process7834 Financial Review The review the Financial requirements	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likly Due to Update <div>1.Negligible ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q23	 Process27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likly Due to Update <div>3.Serious ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q24	 Process26 Company Resources Overview of the Company using various data Reporting Screens	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likly Due to Update <div>3.Serious ▼</div> Action Required:	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>





No Action
Required

53797Q25	 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.	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>1.Negligible ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q26	 Process5877 Review Company Data To review the numbers of various departments. Showing increasing / reducing staff requirements	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>3.Serious ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q27	 Process7070 Management Review To discuss any problems, to assess work load and staffing. To review issues.	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>2.Minor ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q28	 Process5887 Review ISO/EN Documents To Keep Products and Services up-to date with current regulations and standards	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>2.Remote ▾</div> Risk Likly Due to Update <div>2.Minor ▾</div> Action Required:	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>





No Action
Required

53797Q29	 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	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>4.Critical ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q30	 Process6866 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? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>1.Negligible ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q31	 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.	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>3.Occasional ▾</div> Risk Likly Due to Update <div>1.Negligible ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q32	 Process7093 BSI Audits Calander Review of outstanding Audits	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>1.Negligible ▾</div> Action Required:	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>





No Action
Required

53797Q33	 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? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likly Due to Update</div> <div>1.Negligible ▾</div> <div>Action Required: No Action Required</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q34	 Process7138 Non Conformance Issues Any New QC21 Forms To review any new QC 21 Forms	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likly Due to Update</div> <div>3.Serious ▾</div> <div>Action Required: No Action Required</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q35	 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	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likly Due to Update</div> <div>3.Serious ▾</div> <div>Action Required: No Action Required</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q36	 Process7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems.	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likly Due to Update</div> <div>3.Serious ▾</div> <div>Action Required:</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

No Action
Required





53797Q37	 Process7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats.	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likely Due to Update</div> <div>2.Minor ▾</div> <div>Action Required: No Action Required</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q38	 Process57 Temporary Stock Notices To Review Memos on Stock references tagged as Temporary	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likely Due to Update</div> <div>2.Minor ▾</div> <div>Action Required: No Action Required</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q39	 Process5854 Stock FAQ Admin List To update and maintain the Stock FAQ list	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likely Due to Update</div> <div>1.Negligible ▾</div> <div>Action Required: No Action Required</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q40	 Process6871 ISO14001 Environmental management systems Not yet Applied Rolling Issue to see if we should apply this standard in the future	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likely Due to Update</div> <div>1.Negligible ▾</div> <div>Action Required:</div>	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

No Action
Required





53797Q41	 Process7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likely Due to Update <div>1.Negligible ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q42	 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? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likely Due to Update <div>1.Negligible ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q43	 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.	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likely Due to Update <div>1.Negligible ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q44	 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,	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>1.Improbable ▼</div> Risk Likely Due to Update <div>2.Minor ▼</div> Action Required:	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

print new PDF, and upload on top of the old summary

No Action
Required





53797Q45	 Process7878 Review Possible Upcoming Regulation Changes Review possible legal / regulator changes that might affect Viamed / VST	Does Update Affect? <div>No</div>	Risk Frequency due to Update 3.Occasional Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q46	 Process7885 Audit 04 Accounts and Finance Carry out Audit 04 Accounts for Both VST and Viamed	Does Update Affect? <div>No</div>	Risk Frequency due to Update 2.Remote Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q47	 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? <div>No</div>	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q48	 Process7888 Review Processes Linked To VOPs And Audits Ensure All Sub Processes are linked to a VOP and an Audit.	Does Update Affect? <div>No</div>	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required:	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

No Action
Required

53797Q49	 Process7965 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? <div>No ▼</div>	Risk Frequency due to Update <div>2.Remote ▼</div> Risk Likly Due to Update <div>2.Minor ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q50	 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? <div>No ▼</div>	Risk Frequency due to Update <div>2.Remote ▼</div> Risk Likly Due to Update <div>1.Negligible ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q51	 Process7877 Disaster Planning To Plan for disaster	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>3.Occasional ▼</div> Risk Likly Due to Update <div>1.Negligible ▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q52	 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	Does Update Affect? <div>No ▼</div>	Risk Frequency due to Update <div>2.Remote ▼</div> Risk Likly Due to Update <div>1.Negligible ▼</div> Action Required:	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

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

No Action
Required

53797Q53	 Process 11 Distribution Of Mail Distributing incoming post to correct person Current Known Risk Royal Mail fail to deliver post Current Likly 3 Current Frequency 1	Does Update Affect? <div>No ▾</div>	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 <div></div>	Further Action Required on Issue <div></div>
53797Q54	 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	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q55	 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	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
53797Q56	 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	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

Action
Required:
No Action
Required

53797Q57	<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>	<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 if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q58	<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>	<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 if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q59	<p>🔍ProcessProcess 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>	<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 if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q60	<p>🔍ProcessProcess 36 Emailing Of Invoices Invoices are emailed to customers</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

Current Known Risk Computer or network failure
Current Likly 2 Current Frequency 1

to Update

2.Minor ▼

Action

Required:

No Action

Required

53797Q61	<p>🔍ProcessProcess 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 traces will show as shipped. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼</p> <p>Risk Likly Due to Update 2.Minor ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q62	<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 ▼</p> <p>Risk Likly Due to Update 2.Minor ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q63	<p>🔍ProcessProcess 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>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼</p> <p>Risk Likly Due to Update 2.Minor ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q64	<p>🔍ProcessProcess 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</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼</p> <p>Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

Current Known Risk Computer/network breakdown

Current Likly 2 Current Frequency 1

to Update

2.Minor ▼

Action

Required:

No Action

Required

53797Q65	<p>🔍ProcessProcess 5876</p> <p>E.Commerce Cardea And Multiquote</p> <p>To Collect E.Commerce Cardea And Multiquote Orders</p> <p>Current Known Risk Orders go unnoticed</p> <p>Current Likly 1 Current Frequency 1</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:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q66	<p>🔍ProcessProcess 5877</p> <p>Review Company Data</p> <p>To review the numbers of various departments.</p> <p>Showing increasing / reducing staff requirements</p> <p>Current Known Risk incorrect staff levels</p> <p>Current Likly 3 Current Frequency 1</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:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q67	<p>🔍ProcessProcess 5881</p> <p>Training Records Review</p> <p>Keep Staff Training records upto date</p> <p>Current Known Risk Keep enough trained staff to perform our tasks</p> <p>Current Likly 2 Current Frequency 1</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>2.Minor ▼</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q68	<p>🔍ProcessProcess 5882</p> <p>Send Post To Humanmed</p> <p>Humanedmed post is received, it needs to be forwarded to Humanmed UK Sales Manager</p>	<p>Does Update Affect?</p> <p>No ▼</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▼</p> <p>Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

Current Known Risk Post is not sent
Current Likly 4 Current Frequency 1

to Update

4.Critical ▼

Action

Required:

No Action

Required

53797Q69	<p>🔍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 ▼</p> <p>Risk Likly Due to Update 2.Minor ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q70	<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>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼</p> <p>Risk Likly Due to Update 4.Critical ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q71	<p>🔍ProcessProcess 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 2</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 2.Remote ▼</p> <p>Risk Likly Due to Update 2.Minor ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q72	<p>🔍ProcessProcess 5893 Answering Website Questions Answering any questions that are asked via the website from within Intrastats Current Known Risk Computer/network breakdown</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼</p> <p>Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

Current Likly 1 Current Frequency 1

to Update

1.Negligible ▾

Action

Required:

No Action

Required

53797Q73 🔍 ProcessProcess 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
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 if
required

Further Action Required
on Issue

53797Q74 🔍 ProcessProcess 5895
Completing Office Job List
Ensuring that the allocated tasks are being completed
Current Known Risk Office staff are too busy
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 if
required

Further Action Required
on Issue

53797Q75 🔍 ProcessProcess 5899
Proforma And Quote Chasing
Chase outstanding Quotes and Proformas
Current Known Risk Computer/network breakdown
Not chased up.
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 if
required

Further Action Required
on Issue

53797Q76 🔍 ProcessProcess 5901
Link Call Log Contacts To The CRM
To link new calls to Contacts in the CRM

Does
Update
Affect?
No ▾

Risk Frequency
due to Update
1.Improbable ▾

Risk Likly Due

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1		to Update 2.Minor ▾ Action Required: No Action Required		
53797Q77	🔍ProcessProcess 5913 Check For Humanmed Orders In Logistics Mailbox Checking the logistics mailbox from within and the main inbox for outstanding Humanmed orders. Current Known Risk Computer/network breakdown 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 if required	Further Action Required on Issue
53797Q78	🔍ProcessProcess 5943 Check Cardea And Multiquote Checking the Cardea and Multiquote websites for outstanding orders or requests Current Known Risk Computer/network breakdown 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 if required	Further Action Required on Issue
53797Q79	🔍ProcessProcess 5949 Filling Credit Card Slips Inputting the accurate data on to our pre-printed credit card slips for processing on dispatch of good. Secure storing and processing Current Known Risk incorrect information slips left unsecured 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 if required	Further Action Required on Issue
53797Q80	🔍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	Does Update Affect? No ▾ Risk Frequency due to Update 2.Remote ▾ Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

customers.
Current Likly 2 Current Frequency 2

to Update

2.Minor ▼

Action

Required:

No Action

Required

53797Q81 🔍 Process 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 Frequency
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

53797Q82 🔍 Process 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?

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 if
required

Further Action Required
on Issue

53797Q83 🔍 Process 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

Does
Update
Affect?

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 if
required

Further Action Required
on Issue

53797Q84 🔍 Process 6931
Customer Complaints
Review the Customer Complaints Heading
Current Known Risk things are not followed up in a timely manner or are

Does
Update
Affect?

No ▼

Risk Frequency
due to Update

3.Occasional ▼

Risk Likly Due

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

missed
Current Likly 1 Current Frequency 3

to Update
1.Negligible ▾
Action
Required:
No Action
Required

53797Q85	<p>🔍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</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 if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q86	<p>🔍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</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 if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q87	<p>🔍ProcessProcess 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>	<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 if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q88	<p>🔍ProcessProcess 7091 Calibration Index To ensure that all equipment that requires calibration is done. In the correct timescale and manor.</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 2.Remote ▾ Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

	<p>Current Known Risk That equipment we use to may not be calibrated when we need it.</p> <p>Current Likly 1 Current Frequency 2</p>	<p>to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p> <p>No Action Required</p>		
53797Q89	<p>🔍ProcessProcess 7199</p> <p>Non Conformities Review Viamed</p> <p>To review any non conformances created during the previous month, and produce a non conformance report.</p> <p>Review history of non conformances and see if there has been any improvement.</p> <p>Current Known Risk Non conformances go unfixed</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? No ▾</p> <p>Risk Frequency due to Update 2.Remote ▾</p> <p>Risk Likly Due to Update 2.Minor ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q90	<p>🔍ProcessProcess 7670</p> <p>Humanmed general Issues</p> <p>Review of Humanmed sales and orders and clear any duplicates or problems.</p> <p>Current Known Risk That there are duplicate orders o the system due to errors.</p> <p>Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? No ▾</p> <p>Risk Frequency due to Update 1.Improbable ▾</p> <p>Risk Likly Due to Update 3.Serious ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q91	<p>🔍ProcessProcess 7671</p> <p>Humanmed Non Conformances</p> <p>Humanmed Non Conformances</p> <p>Current Known Risk non conformations not logged.</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? No ▾</p> <p>Risk Frequency due to Update 2.Remote ▾</p> <p>Risk Likly Due to Update 2.Minor ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q92	<p>🔍ProcessProcess 7673</p> <p>Check Expiry Dated Stock</p> <p>To check that all the stock on the selves are within their use by dates.</p>	<p>Does Update Affect? No ▾</p> <p>Risk Frequency due to Update 2.Remote ▾</p> <p>Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

Current Known Risk Stock being dispatched that is past its date.
Current Likly 1 Current Frequency 2

to Update

1.Negligible ▼

Action

Required:

No Action

Required

53797Q93	<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 if required</p>	<p>Further Action Required on Issue</p>
53797Q94	<p>🔍ProcessProcess 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 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. 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 if required</p>	<p>Further Action Required on Issue</p>
53797Q95	<p>🔍ProcessProcess 7678 Check Catalog 360 Circle For Quotes And Orders Checking the Catalog 360 Circle website for outstanding orders or requests 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 if required</p>	<p>Further Action Required on Issue</p>
53797Q96	<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.</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

Current Known Risk That a customer is told we have stock and then we are unable to ship.
Current Likly 2 Current Frequency 1

to Update

2.Minor ▾

Action

Required:

No Action

Required

53797Q97	<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 ▾</p> <p>Risk Likly Due to Update 1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q98	<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 ▾</p> <p>Risk Likly Due to Update 1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q99	<p>🔍ProcessProcess 7686 Thorough Checking Of Awaiting Action Tray 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 ▾</p> <p>Risk Likly Due to Update 2.Minor ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
53797Q100	<p>🔍ProcessProcess 7690 Ship Repairs Review the Repairs completed shelf and ship those items that are ready for return to the customer.</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾</p> <p>Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

Current Known Risk That a repair will be missed
Current Likly 2 Current Frequency 1

to Update

2.Minor ▼

Action

Required:

No Action

Required

53797Q101 🔍 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

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 if
required

Further Action Required
on Issue

53797Q102 🔍 ProcessProcess 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

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 if
required

Further Action Required
on Issue

53797Q103 🔍 ProcessProcess 7699
Shred Sensitive Paperwork In JL Office
Shredding of sensitive information
Current Known Risk Broken shredder
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 if
required

Further Action Required
on Issue

53797Q104 🔍 ProcessProcess 7709
Delivered not Invoiced
Ensure invoices are generated for shipped orders
Current Known Risk Computer/network breakdown

Does
Update
Affect?

No ▼

Risk Frequency
due to Update

2.Remote ▼

Risk Likly Due

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

delivery is missed and remains un invoiced.
Current Likly 2 Current Frequency 2

to Update

2.Minor ▼

Action

Required:

No Action

Required

53797Q105 🔍 ProcessProcess 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

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 if
required

Further Action Required
on Issue

53797Q106 🔍 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?
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 if
required

Further Action Required
on Issue

53797Q107 🔍 ProcessProcess 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

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 if
required

Further Action Required
on Issue

53797Q108 🔍 ProcessProcess 7741
Review Ethical Policy
Review the current Ethical Policy in intrastats

Does
Update
Affect?
No ▼

Risk Frequency
due to Update
1.Improbable ▼

Risk Likly Due

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

Current Known Risk That something is missed that we would like to include Current Likly 1 Current Frequency 1		to Update 1.Negligible ▾ Action Required: No Action Required		
53797Q109 ProcessProcess 7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file. Check the File is being Maintained and any relevant documentation is in the File. Current Known Risk Customer Complaints could be missed or not filed correctly 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 if required	Further Action Required on Issue
53797Q110 ProcessProcess 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 if required	Further Action Required on Issue
53797Q111 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 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 if required	Further Action Required on Issue
53797Q112 ProcessProcess 7749	Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required

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

Update due to Update	required	on Issue
Affect? 2.Remote		
No	Risk Likly Due to Update	
	2.Minor	
	Action Required:	
	No Action Required	

53797Q113 ProcessProcess 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

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect? 1.Improbable			
No	Risk Likly Due to Update		
	2.Minor		
	Action Required:		
	No Action Required		

53797Q114 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

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect? 1.Improbable			
No	Risk Likly Due to Update		
	3.Serious		
	Action Required:		
	No Action Required		

53797Q115 ProcessProcess 7758
Check For GHX Orders
Check the emails for orders from GHX
Current Known Risk Computer/network breakdown
Current Likly 2 Current Frequency 1

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect? 1.Improbable			
No	Risk Likly Due to Update		
	2.Minor		
	Action Required:		
	No Action Required		

53797Q116 ProcessProcess 7760

Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required
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<p>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>Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>required</p> <div></div>	<p>on Issue</p> <div></div>
<p>53797Q117 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? 1.Improbable ▾ No ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>53797Q118 ProcessProcess 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>	<p>Does Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>53797Q119 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? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>53797Q120 ProcessProcess 7795</p>	<p>Does</p>	<p>Risk Frequency</p>	<p>Notes On Risk / Benefits statement if Further Action Required</p>

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

Update due to Update required

Affect? 1.Improbable ▼

No ▼ Risk Likly Due to Update

1.Negligible ▼


Action

Required:

No Action

Required

on Issue

53797Q121  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

Does Update Risk Frequency

Affect? 1.Improbable ▼

No ▼ Risk Likly Due to Update

2.Minor ▼

Action


Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q122  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 Risk Frequency

Affect? 2.Remote ▼

No ▼ Risk Likly Due to Update

1.Negligible ▼

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q123  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 Risk Frequency

Affect? 2.Remote ▼

No ▼ Risk Likly Due to Update

1.Negligible ▼

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q124  ProcessProcess 7822

Does Risk Frequency

Notes On Risk / Benefits statement if

Further Action Required

<p>Review Oxylink Stock To check we have the stock available to supply our customer Oxylink.</p> <p>NOTE THIS PROCESS HAS BEEN STOPPED.</p> <p>Part number has been superseded Current Known Risk The we do not have the stock needed to satisfy the orders for this customer. Current Likly 3 Current Frequency 1</p>	<p>Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>required</p> <div></div>	<p>on Issue</p> <div></div>
<p>53797Q125 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</p>	<p>Does Update Affect? 2.Remote No Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>53797Q126 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>	<p>Does Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>53797Q127 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>	<p>Does Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>53797Q128 ProcessProcess 7830</p>	<p>Does</p>	<p>Risk Frequency</p>	<p>Notes On Risk / Benefits statement if Further Action Required</p>

Review Q.A. Failures Report

To review the Quantities of Failed product per Stock reference Passing through the Q.A. system

Current Known Risk No risk

Current Likly 3 Current Frequency 1

Update
Affect?

due to Update
1.Improbable ▼

No ▼

Risk Likly Due
to Update

3.Serious ▼

Action

Required:

No Action

Required

required

on Issue

53797Q129  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?

Risk Frequency
due to Update
1.Improbable ▼

No ▼

Risk Likly Due
to Update

3.Serious ▼

Action


Required:

No Action

Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

53797Q130  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

Does
Update
Affect?

Risk Frequency
due to Update
1.Improbable ▼

No ▼

Risk Likly Due
to Update

2.Minor ▼

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

53797Q131  Process 7834

Financial Review

The review the Financial requirements

Current Known Risk Non

Current Likly 1 Current Frequency 1

Does
Update
Affect?

Risk Frequency
due to Update
1.Improbable ▼

No ▼

Risk Likly Due
to Update

1.Negligible ▼

Action





Required:

















No Action

Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

53797Q132	 Process 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? <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 if required	Further Action Required on Issue
53797Q133	 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? <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 if required	Further Action Required on Issue
53797Q134	 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? <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 if required	Further Action Required on Issue
53797Q135	 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 Rolling ISsue, No Risk Current Likly 3 Current Frequency 1	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 if required	Further Action Required on Issue

53797Q136  Process 7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised Current Known Risk Rolling ISsue, No Risk Current Likly 3 Current Frequency 1	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 if required <div data-bbox="1402 140 1832 300"></div>	Further Action Required on Issue <div data-bbox="1850 140 2152 172"></div>
53797Q137  Process 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 Rolling ISsue, No Risk Current Likly 3 Current Frequency 1	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 if required <div data-bbox="1402 501 1832 660"></div>	Further Action Required on Issue <div data-bbox="1850 501 2152 533"></div>
53797Q138  Process 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 Rolling ISsue, No Risk Current Likly 3 Current Frequency 1	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 if required <div data-bbox="1402 861 1832 1021"></div>	Further Action Required on Issue <div data-bbox="1850 861 2152 893"></div>
53797Q139  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? <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 if required <div data-bbox="1402 1222 1832 1382"></div>	Further Action Required on Issue <div data-bbox="1850 1222 2152 1254"></div>

53797Q140	<p>ProcessProcess 7847 Health And Safety Review Perform HSE Risk Assessment,</p> <p>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.</p> <p>Send new Issue to Projects Asking if New HSE implications have arisen from new products.</p> <p>Review Online the Local Community Risk Register.</p> <p>Check the Viamed Overall Risk Analysis Program Document in the Index to check its still current. Current Known Risk HSE Risks to Staff and business Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q141	<p>ProcessProcess 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</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q142	<p>ProcessProcess 7849 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 Risk Frequency Update due to Update Affect? 3.Occasional ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
53797Q143	<p>ProcessProcess 7871 Review Exclusion From Viamed 13485:2016 And VST 9001:2015 To review the Exclusions / boundaries to ISO 13485:2016 for Viamed</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

Current Known Risk Something is missed.
Current Likly 1 Current Frequency 1

to Update

1.Negligible ▾

Action

Required:

No Action

Required

53797Q144 🔍 ProcessProcess 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

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 if
required

Further Action Required
on Issue

53797Q145 🔍 ProcessProcess 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

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 if
required

Further Action Required
on Issue

53797Q146 🔍 ProcessProcess 7877
Disaster Planning
To Plan for disaster
Current Known Risk Total failure
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 if
required

Further Action Required
on Issue

53797Q147 🔍 ProcessProcess 7878
Review Possible Upcoming Regulation Changes

Does
Update

Risk Frequency
due to Update

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

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

Affect?

3.Occasional

No

Risk Likly Due to Update

1.Negligible

Action Required:

No Action Required

53797Q148 ProcessProcess 7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications
Current Known Risk task not carried out
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 if required

Further Action Required on Issue

53797Q149 Document ID22371 Chart 36 Risk Management Existing Products Is Related to this document

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 if required

Further Action Required on Issue

53797Q150 Document ID74871 Need Risks and Expectations of External Parties Viamed Is Related to this document

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 if required

Further Action Required on Issue

53797Q151 Document ID22842 VM3COP00.01 Company objectives Is Related to this document

Does Update

Risk Frequency due to Update

Notes On Risk / Benefits statement if required

Further Action Required on Issue

Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q152 Document ID17423 VM3COP02 Organisation Responsibilities Viamed Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q153 Document ID13954 VM3COP02 Organisation VST Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q154 Document ID69692 VM3COP02.01 Boundaries ISO 9001:2015 VST Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q155 Document ID74788 VM3COP10.02 Product Recall locate products out in the Field Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q156 Document ID8106 VM3COP18 Post Market Surveillance Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q157 Document ID43166 VM3COP20.064 Atlas List Invoices of a Company Between dates Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q158 Document ID47771 VM3COP24.00 Viamed Overall Risk Analysis Program Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q159 Document ID15453 VM3COP27.12 Clinical Evaluation Risk assessment Technical Files Is Related to this document

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q160 Document ID16995 VM3COP27.17 Complete Auto_calender Issues Is Related to this document	Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
	Affect?	1.Improbable ▼		
	No ▼	Risk Likly Due to Update		
		1.Negligible ▼		
		Action Required:		
		No Action Required		

53797Q161 Document ID17082 VM3COP27.36 Auto Close Issues Is Related to this document	Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
	Affect?	1.Improbable ▼		
	No ▼	Risk Likly Due to Update		
		1.Negligible ▼		
		Action Required:		
		No Action Required		

53797Q162 Document ID24926 VM3COP27.38 Applying statistics to Viamed products Is Related to this document	Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
	Affect?	1.Improbable ▼		
	No ▼	Risk Likly Due to Update		
		1.Negligible ▼		
		Action Required:		
		No Action Required		

53797Q163 Document ID72870 VM3COP60.04 Viamed Disaster Planning Business Continuity Plan Reports Is Related to this document	Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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Affect?	1.Improbable ▼		
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q164 Document ID74819 VM3COP60.06 BUSINESS CONTINUITY PLAN
Contingency Plan Viamed VST Vandagraph Is Related to this document

Does Update Affect?	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
No ▼	1.Improbable ▼		
	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q165 Does Generic CE File Attached to All Technical file #2
Of type 5 require any Notificaions and/or Risk assesment updates

Does Update Affect?	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
No ▼	1.Improbable ▼		
	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required:		
	No Action Required		

53797Q166 Final Notes

No ISO Procedures or Process are negativaly affected by updating this document with the new document proposed

SAVE FORM