

Document Audit 14 Complaints and Corrective Actions Revision ID41228

Suggested Upload Document Name: **Risk Assessment For Updating Document ID41228**

Completed by Helen Lamb 25 Nov 2021

Reason for Risk Assessment

updated processes for 2021. No new risk

Document Audit 14 Complaints and Corrective Actions Revision ID41228 Is linked to the Following Standards and processes

Risk Assessment Question ID41228	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further on Issue
41228Q0 Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significant change to any ISO Certifications	Does Update Affect? No	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	Further on Issue
41228Q1 Viamed Ltd ISO13485:2016 Section: 7.2.3 Communication The organization shall plan and document arrangements for communicating with customers in relation to: a) product information; b) enquiries, contracts or order handling, including amendments; c) customer feedback, including complaints; d) advisory notices. The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.	Does Update Affect? No	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	Further on Issue
41228Q2 Viamed Ltd ISO13485:2016 Section: 7.5.4 Servicing activities If servicing of the medical device is a specified requirement, the organization shall document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met. The organization shall analyse records of servicing activities carried out by the organization or its supplier: a) to determine if the information is to be handled as a complaint; b) as appropriate, for input to the improvement process. Records of servicing activities carried out by the organization or its supplier shall be maintained (see 4.2.5).	Does Update Affect? No	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	Further on Issue
41228Q3 Viamed Ltd ISO13485:2016 Section: 8.2.1 Feedback As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented. The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.	Does Update Affect? No	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	Further on Issue
41228Q4 Viamed Ltd ISO13485:2016 Section: 8.2.2 Complaint handling The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due	Notes On Risk / Benefits statement if required	Further on Issue

These procedures shall include at a minimum requirements and responsibilities for:

- a) receiving and recording information;
- b) evaluating information to determine if the feedback constitutes a complaint;
- c) investigating complaints;
- d) determining the need to report the information to the appropriate regulatory authorities;
- e) handling of complaint-related product;
- f) determining the need to initiate corrections or corrective actions.

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained (see 4.2.5).

to Update

1.Negligible ▾

Action

Required:

No Action

Required

41228Q5	<p>Viamed Ltd ISO13485:2016 Section: 8.2.3</p> <p>Reporting to regulatory authorities</p> <p>If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.5).</p>	Does Update Affect? No ▾	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	Further on Issue
41228Q6	<p>Viamed Ltd ISO13485:2016 Section: 8.3.3</p> <p>Actions in response to nonconforming product detected after delivery</p> <p>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken shall be maintained (see 4.2.5).</p> <p>The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5).</p>	Does Update Affect? No ▾	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	Further on Issue
41228Q7	<p>Viamed Ltd ISO13485:2016 Section: 8.5.2</p> <p>Corrective action</p> <p>The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for:</p> <ul style="list-style-type: none">a) reviewing nonconformities (including complaints);b) determining the causes of nonconformities;c) evaluating the need for action to ensure that nonconformities do not recur;d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;f) reviewing the effectiveness of corrective action taken <p>Records of the results of any investigation and action taken shall be maintained (see 4.2.5).</p>	Does Update Affect? No ▾	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	Further on Issue
41228Q8	<p>Viamed Ltd ISO13485:2016 Section: 8.5.3</p> <p>Preventive action</p> <p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for:</p> <ul style="list-style-type: none">a) determining potential nonconformities and their causes;b) evaluating the need for action to prevent occurrence of nonconformities;c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;e) reviewing the effectiveness of the preventive action taken, as appropriate. <p>Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).</p>	Does Update Affect? No ▾	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	Further on Issue

41228Q9	<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.</p> <p>In determining the extent of post-delivery activities that are required, the organization shall consider:</p> <ol style="list-style-type: none"> statutory and regulatory requirements; the potential undesired consequences associated with its products and services; the nature, use and intended lifetime of its products and services; customer requirements; 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? 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>	<p>Further on Issues</p>
41228Q10	<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>	<p>Further on Issues</p>
41228Q11	<p>VST Ltd ISO9001:2015 Section: 10.1</p> <p>General</p> <p>The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.</p> <p>These shall include:</p> <ol style="list-style-type: none"> improving products and services to meet requirements as well as to address future needs and expectations; correcting, preventing or reducing undesired effects; improving the performance and effectiveness of the quality management system. <p>NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.</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>	<p>Further on Issues</p>
41228Q12	<p>VST Ltd ISO9001:2015 Section: 10.2.1</p> <p>When a nonconformity occurs, including any arising from complaints, the organization shall:</p> <ol style="list-style-type: none"> react to the nonconformity and, as applicable: <ol style="list-style-type: none"> take action to control and correct it; deal with the consequences; evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: <ol style="list-style-type: none"> reviewing and analysing the nonconformity; determining the causes of the nonconformity; determining if similar nonconformities exist, or could potentially occur; implement any action needed; review the effectiveness of any corrective action taken; update risks and opportunities determined during planning, if necessary; make changes to the quality management system, if necessary. <p>Corrective actions shall be appropriate to the effects of the nonconformities encountered.</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>	<p>Further on Issues</p>
41228Q13	<p>Process7743</p> <p>Customer Complaints Paper File</p> <p>Major Customer Complaints get escalated to Paper Customer Complaints file.</p> <p>Check the File is being Maintained and any relevant documentation is in the File.</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>2.Minor</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further on Issues</p>
41228Q14	<p>Process7199</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>Does Update Affect? No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likely Due to Update</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further on Issues</p>









<div>Review history of non conformances and see if there has been any improvement.</div>	<div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	
<div>41228Q15</div> <div>Process7671</div> <div>Humanmed Non Conformances</div> <div>Humanmed Non Conformances</div>	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>2.Remote</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div> <div>Further on Issue</div>
<div>41228Q16</div> <div>Process7838</div> <div>Review VIAMED Feedback - Customer Feedback Negative</div> <div>Review Customer Feedback Negative</div>	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div> <div>Further on Issue</div>
<div>41228Q17</div> <div>Process7839</div> <div>Review VIAMED Feedback - Customer Complaints</div> <div>To Review Viamed Customer Complaints</div>	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div> <div>Further on Issue</div>
<div>41228Q18</div> <div>Process7840</div> <div>Review VST Feedback - Customer Feedback Negative</div> <div>To review Negative feedback form Products</div> <div>see if Non Conformance or customer Complaints need to be raised</div>	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div> <div>Further on Issue</div>
<div>41228Q19</div> <div>Process7841</div> <div>Review VST Feedback - Customer Complaints</div> <div>To review Customer Complaints</div> <div>see if Non Conformance need to be raised</div>	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div> <div>Further on Issue</div>
<div>41228Q20</div> <div>Process7842</div> <div>Review VIAMED Product Feedback Negative</div> <div>To review Negative feedback form Products</div> <div>see if Non Conformance or customer Complaints need to be raised</div>	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div> <div>Further on Issue</div>
<div>41228Q21</div> <div>Process7843</div> <div>Review VST Product Feedback Negative</div> <div>To review Negative feedback form Products</div> <div>see if Non Conformance or customer Complaints need to be raise</div>	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div> <div>Further on Issue</div>

41228Q22	Process7849 Review Product Failures New Codes Review the Customer Returns and Review Product Failures New Codes	Does Update Affect? No ▾	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	Further on Issues
41228Q23	Process6931 Customer Complaints Review the Customer Complaints Heading	Does Update Affect? No ▾	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	Further on Issues
41228Q24	Process7934 Test Website Questions Test the integration of the website submitted questions to intrastats	Does Update Affect? No ▾	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	Further on Issues
41228Q25	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? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likely Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q26	Process7264 VST Management Meeting Non Conformance Issues To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement.	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likely Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q27	ProcessProcess 9 Distribution Of Faxes Distribute recieved faxes Current Known Risk lost faxes Current Likly 1 Current Frequency 1	Does Update Affect? No ▾	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	Further on Issues
41228Q28	ProcessProcess 11 Distribution Of Mail Distibuting incoming post to correct person Current Known Risk Royal Mail fail to deliver post Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likely Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q29	ProcessProcess 36 Emailing Of Invoices Invoices are emailed to customers Current Known Risk Computer or network failure Current Likly 2 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likely Due to Update	Notes On Risk / Benefits statement if required	Further on Issues

			<div>2.Minor</div> <div>Action Required: No Action Required</div>		
41228Q30	<div><div>🔍</div><div>Process</div><div>Process 5850</div></div> <div>Purchase Order Log</div> <div>Check the PO log is up to date with confirmations and expected shipping dates</div> <div>Current Known Risk The order is not checked and the supplier has not received it ergo we do not receive the order</div> <div>Current Likly 2 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>2.Minor</div> <div>Action Required: No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issu</div>
41228Q31	<div><div>🔍</div><div>Process</div><div>Process 5857</div></div> <div>Customer Service Logs</div> <div>Ensuring customer onsite service visits are completed</div> <div>Current Known Risk Engineer or equipment is unavailable</div> <div>Current Likly 2 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>2.Minor</div> <div>Action Required: No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issu</div>
41228Q32	<div><div>🔍</div><div>Process</div><div>Process 5875</div></div> <div>Check Paypal For Orders</div> <div>Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox</div> <div>Current Known Risk Computer/network breakdown</div> <div>Current Likly 2 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>2.Minor</div> <div>Action Required: No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issu</div>
41228Q33	<div><div>🔍</div><div>Process</div><div>Process 5876</div></div> <div>E.Commerce Cardea And Multiquote</div> <div>To Collect E.Commerce Cardea And Multiquote Orders</div> <div>Current Known Risk Orders go unnoticed</div> <div>Current Likly 1 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>1.Negligible</div> <div>Action Required: No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issu</div>
41228Q34	<div><div>🔍</div><div>Process</div><div>Process 5877</div></div> <div>Review Company Data</div> <div>To review the numbers of various departments.</div> <div>Showing increasing / reducing staff requirements</div> <div>Current Known Risk incorrect staff levels</div> <div>Current Likly 3 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>3.Serious</div> <div>Action Required: No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issu</div>
41228Q35	<div><div>🔍</div><div>Process</div><div>Process 5892</div></div> <div>Checking EBay And Amazon For Orders And Messages</div> <div>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.</div> <div>Current Known Risk Computer/network breakdown</div> <div>Current Likly 2 Current Frequency 2</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>2.Remote</div> <div>Risk Likly Due to Update</div> <div>2.Minor</div> <div>Action Required: No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issu</div>
41228Q36	<div><div>🔍</div><div>Process</div><div>Process 5893</div></div> <div>Answering Website Questions</div> <div>Answering any questions that are asked via the website from within Intrastats</div> <div>Current Known Risk Computer/network breakdown</div> <div>Current Likly 1 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>1.Negligible</div> <div>Action Required: No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issu</div>

41228Q37	Process Process 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 on Issues
41228Q38	Process Process 5901 Link Call Log Contacts To The CRM To link new calls to Contacts in the CRM 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 on Issues
41228Q39	Process Process 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 on Issues
41228Q40	Process Process 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 on Issues
41228Q41	Process Process 6866 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 Current Known Risk Review 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 on Issues
41228Q42	Process Process 7091 Calibration Index To ensure that all equipment that requires calibration is done. In the correct timescale and manor. Current Known Risk That equipment we use to may not be calibrated when we need it. 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 on Issues
41228Q43	Process Process 7138 Non Conformance Issues Any New QC21 Forms To review any new QC 21 Forms Current Known Risk potential non conformances go undetected 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 on Issues
41228Q44	Process Process 7199 Non Conformities Review Viamed To review any non conformances created during the previous month, and produce a non conformance report.	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further on Issues

	<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>	<div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>			
41228Q45	<p>Process 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>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issues</div>
41228Q46	<p>Process 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>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>2.Remote</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issues</div>
41228Q47	<p>Process 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>Current Known Risk Stock being dispatched that is pasts its date.</p> <p>Current Likly 1 Current Frequency 2</p>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>2.Remote</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issues</div>
41228Q48	<p>Process 7678</p> <p>Check Catalog 360 Circle For Quotes And Orders</p> <p>Checking the Catalog 360 Circle website for outstanding orders or requests</p> <p>SYSTEM NO LONGER USED</p> <p>Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issues</div>
41228Q49	<p>Process 7686</p> <p>Thorough Checking Of Awaiting Action Tray</p> <p>Check that outstanding orders with unresolved issues are being followed up and addressed</p> <p>Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issues</div>
41228Q50	<p>Process 7693</p> <p>Collect Repair Filing From Warehouse</p> <p>Collect the filing form the warehouse</p> <p>Current Known Risk paperwork has been missed</p> <p>Current Likly 1 Current Frequency 1</p>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issues</div>
41228Q51	<p>Process 7735</p> <p>Ensure SOR's Are Followed Up</p> <p>Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and the item(s) is returned as appropriate</p> <p>Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further on Issues</div>

41228Q52	 Process 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 <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update 2.Minor <input type="checkbox"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q53	 Process 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 <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update 2.Minor <input type="checkbox"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q54	 Process 7758 Check For GHX Orders Check the emails for orders from GHX Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1	Does Update Affect? No <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update 2.Minor <input type="checkbox"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q55	 Process 7760 Send Service Offers Send letters to existing customers to remind them that a service is due on their equipment Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1	Does Update Affect? No <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update 1.Negligible <input type="checkbox"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q56	 Process 7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats. Current Known Risk not clear regularly, accidental usage of an old ORDER number generated by mistake Current Likly 2 Current Frequency 1	Does Update Affect? No <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update 2.Minor <input type="checkbox"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q57	 Process 7792 Shipped Order Success Report A report is generated from figures in Intrastats to display how many orders have been shipped without errors Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1	Does Update Affect? No <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update 2.Minor <input type="checkbox"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q58	 Process 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 Affect? No <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update 2.Minor <input type="checkbox"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q59	 Process 7798 Orders And Items Shipped Per Month Review the orders and items shipped per month Current Known Risk Problem with report Current Likly 3 Current Frequency 1	Does Update Affect? No <input type="checkbox"/>	Risk Frequency due to Update 1.Improbable <input type="checkbox"/> Risk Likely Due to Update	Notes On Risk / Benefits statement if required	Further on Issues

			3.Serious		
			Action Required:		
			No Action Required		
41228Q60	<p>Process 7820</p> <p>North Yorkshire Council Waste Transfer</p> <p>The renewal of our waste transfer agreement with North Yorkshire County Council</p> <p>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 manner.</p> <p>Current Likly 1 Current Frequency 2</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</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 on Issues</p>
41228Q61	<p>Process 7821</p> <p>Controlled Waste Description And Transfer</p> <p>The renewal of our waste transfer agreement with our waste disposal companies</p> <p>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 manner.</p> <p>Current Likly 1 Current Frequency 2</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</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 on Issues</p>
41228Q62	<p>Process 7822</p> <p>Review Oxylink Stock</p> <p>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</p> <p>Current Known Risk The we do not have the stock needed to satisfy the orders for this customer.</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 Likely 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>	<p>Further on Issues</p>
41228Q63	<p>Process 7826</p> <p>Goods In Processes</p> <p>To Receive Goods from Suppliers</p> <p>Current Known Risk incorrectly booked in not booked in</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likely 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>	<p>Further on Issues</p>
41228Q64	<p>Process 7830</p> <p>Review Q.A. Failures Report</p> <p>To review the Quantities of Failed product per Stock reference Passing through the Q.A. system</p> <p>Current Known Risk No risk</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 Likely 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>	<p>Further on Issues</p>
41228Q65	<p>Process 7838</p> <p>Review VIAMED Feedback - Customer Feedback Negative</p> <p>Review Customer Feedback Negative</p> <p>Current Known Risk Rolling Issues No risk to process</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 Likely 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>	<p>Further on Issues</p>
41228Q66	<p>Process 7839</p> <p>Review VIAMED Feedback - Customer Complaints</p> <p>To Review Viamed Customer Complaints</p> <p>Current Known Risk Rolling Issue No Risk</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 Likely 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>	<p>Further on Issues</p>

41228Q67	Process 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? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q68	Process 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? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q69	Process 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? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q70	Process 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? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q71	Process Process 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	Does Update Affect? No	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	Further on Issues
41228Q72	Process Process 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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
41228Q73	Process Process 7957 Warehouse Requests Warehouse requests for stock to be reviewed, any shortages to be ordered or produced with a production Job Current Known Risk Stock requirements fulfilled Current Likly 1 Current Frequency 1	Does Update Affect? No	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	Further on Issues
41228Q74	Final Notes Processes updated for 2021 No risk associated				

