

Document VOP 10 Non Conformance, Corrective and Preventive Actions Revision ID88791

Suggested Upload Document Name: **Risk Assesment For Updating Document ID88791**

Completed by [Derek Lamb](#) 06 May 2022

Reason for Risk Assesment

updated section on temperature monitoring,
no stock has limits outside of warehouse operating temperatures

Document VOP 10 Non Conformance, Corrective and Preventive Actions Revision ID88791 Is linked to the Following Standards and processes

Risk Assesment Question ID88791	Does Update Risk on Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
88791Q0 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
88791Q1 Viamed Ltd ISO13485:2016 Section: 8.3.1 General The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.	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

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5)

88791Q2	<p>Viamed Ltd ISO13485:2016 Section: 8.5.1</p> <p>General</p> <p>The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.</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> <div></div>	<p>Further Action Required on Issue</p> <div></div>
88791Q3	<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> <p>a) reviewing nonconformities (including complaints);</p> <p>b) determining the causes of nonconformities;</p> <p>c) evaluating the need for action to ensure that nonconformities do not recur;</p> <p>d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;</p> <p>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;</p> <p>f) reviewing the effectiveness of corrective action taken</p> <p>Records of the results of any investigation and action taken shall be maintained (see 4.2.5).</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> <div></div>	<p>Further Action Required on Issue</p> <div></div>
88791Q4	<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.</p> <p>The organization shall document a procedure to describe requirements for:</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>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

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.
Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

No Action
Required

88791Q5	VST Ltd ISO9001:2015 Section: 7.5.2 Creating and updating 7.5.2 Creating and updating When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy.	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>
88791Q6	VST Ltd ISO9001:2015 Section: 7.5.3 Control of documented information	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>
88791Q7	VST Ltd ISO9001:2015 Section: 9.1.1 General The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the	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>

quality management system.

The organization shall retain appropriate documented information as evidence of the results.

88791Q8	<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> <p>a) improving products and services to meet requirements as well as to address future needs and expectations;</p> <p>b) correcting, preventing or reducing undesired effects;</p> <p>c) improving the performance and effectiveness of the quality management system.</p> <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 1.Improbable ▾</p> <p>Risk Likely Due to Update 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>
88791Q9	<p>VST Ltd ISO9001:2015 Section: 10.2</p> <p>Nonconformity and corrective action</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾</p> <p>Risk Likely Due to Update 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>
88791Q10	<p>VST Ltd ISO9001:2015 Section: 10.2.1</p> <p>When a nonconformity occurs, including any arising from complaints, the organization shall:</p> <p>a) react to the nonconformity and, as applicable:</p> <p>1) take action to control and correct it;</p> <p>2) deal with the consequences;</p> <p>b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:</p> <p>1) reviewing and analysing the nonconformity;</p> <p>2) determining the causes of the nonconformity;</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾</p> <p>Risk Likely Due to Update 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>

- 3) determining if similar nonconformities exist, or could potentially occur;
c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the quality management system, if necessary.
Corrective actions shall be appropriate to the effects of the nonconformities encountered.

88791Q11 VST Ltd ISO9001:2015 Section: 10.2.2

The organization shall retain documented information as evidence of:
a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

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

88791Q12 Process7199

Non Conformities Review Viamed
To review any non conformances created during the previous month, and produce a non conformance report.

Review history of non conformances and see if there has been any improvement.

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

88791Q13 Process7849

Review Product Failures New Codes
Review the Customer Returns and Review Product Failures New Codes

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





88791Q14 Process7874





Review For Latest Version Med Dev 2.12.





Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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<p>To Ensure we have the latest version of Med Dev 2.12. and update management if its been updated</p>	<div> <div>Affect?</div> <div>1.Improbable</div> <div>No</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div> </div> <div></div> <div></div>
<p>88791Q15 Process7264</p> <p>VST Management Meeting Non Conformance Issues 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>	<div> <div>Does Update</div> <div>Risk Frequency due to Update</div> <div>Affect?</div> <div>2.Remote</div> <div>No</div> <div>Risk Likely Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div> </div> <div>Notes On Risk / Benefits statement if required</div> <div>Further Action Required on Issue</div>
<p>88791Q16 ProcessProcess 6866</p> <p>Internal Process Verification Complete Systems Review Review the Internal Process and Verification`s are suitable for the current standards</p> <p>PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20 Current Known Risk Review not carried out Current Likly 1 Current Frequency 1</p>	<div> <div>Does Update</div> <div>Risk Frequency due to Update</div> <div>Affect?</div> <div>1.Improbable</div> <div>No</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div> </div> <div>Notes On Risk / Benefits statement if required</div> <div>Further Action Required on Issue</div>
<p>88791Q17 ProcessProcess 7091</p> <p>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.</p> <p>Current Likly 1 Current Frequency 2</p>	<div> <div>Does Update</div> <div>Risk Frequency due to Update</div> <div>Affect?</div> <div>2.Remote</div> <div>No</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div> </div> <div>Notes On Risk / Benefits statement if required</div> <div>Further Action Required on Issue</div>
<p>88791Q18 ProcessProcess 7138</p>	<div> <div>Does</div> <div>Risk Frequency</div> <div>Notes On Risk / Benefits statement if</div> <div>Further Action Required</div> </div>

<p>Non Conformance Issues Any New QC21 Forms To review any new QC 21 Forms Check existing forms for corrective actions and effectiveness Current Known Risk potential non conformances go undetected 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>	<p>on Issue</p>
<p>88791Q19 Process 7199 Non Conformities Review Viamed To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement. Current Known Risk Non conformances go unfixed Current Likly 2 Current Frequency 2</p>	<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>	<p>Further Action Required on Issue</p>
<p>88791Q20 Process 7671 Humanmed Non Conformances Humanmed Non Conformances Current Known Risk non conformations not logged. 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>	<p>Further Action Required on Issue</p>
<p>88791Q21 Process 7676 PDFing Of Invoices Viamed Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers 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? 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>	<p>Further Action Required on Issue</p>

88791Q22  Process 7693 Collect Repair Filing From Warehouse Collect the filing form the warehouse Current Known Risk paperwork has been missed Current Likly 1 Current Frequency 1	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></div>	Further Action Required on Issue <div></div>
88791Q23  Process 7705 Checking For Uploaded Files Checking if a customer has uploaded an order directly to our website Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 2	Does Update Affect? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="2.Remote"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
88791Q24  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? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
88791Q25  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 2	Does Update Affect? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="2.Remote"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

<p>88791Q26  Process 7782</p> <p>Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats.</p> <p>Current Known Risk not clear regularly, accidental usage of an old ORDER number generated by mistake Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to 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>88791Q27  Process 7822</p> <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>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ 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>
<p>88791Q28  Process 7830</p> <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</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ 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>
<p>88791Q29  Process 7838</p> <p>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</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ 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>

88791Q30  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 <div></div>	Further Action Required on Issue <div></div>
88791Q31  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></div>	Further Action Required on Issue <div></div>
88791Q32  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></div>	Further Action Required on Issue <div></div>
88791Q33  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? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="3.Occasional"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

<p>88791Q34  Process 7857</p> <p>Software Validation Stock Tracking Check</p> <p>To confirm Software Validation Stock Tracking Check, is functioning as expected</p> <p>Current Known Risk Stock gets mislaid in the warehouse</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
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<p>88791Q35 Does Generic CE File Attached to All Technical file #2</p> <p>Of type 5 require any Notificaions and/or Risk assesment updates due to this update</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 Likly 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 style="border: 1px solid #ccc; height: 100px; width: 100%;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid #ccc; height: 30px; width: 100%;"></div>
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<p>88791Q36 Final Notes</p> <div style="border: 1px solid #ccc; padding: 10px; min-height: 100px;"> <p>No ISO Procedures or Process are negativly affected by updating this document with the new document proposed</p> </div>
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SAVE FORM Only saves your progress in filling in above Questions - No feed back to pressing save form button

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