

# Document VM3COP27.46 Non Conformance review (How Too) Revision ID71643

Suggested Upload Document Name: **Risk Assesment For Updating Document ID71643**

Completed by [Derek Lamb](#) 26 Nov 2021

## Reason for Risk Assesment

Made how to simpler to follow,  
does not change ISO Procedure as its a how Too

Document VM3COP27.46 Non Conformance review (How Too) Revision ID71643 Is linked to the Following Standards and processes

Risk Assesment Question ID71643	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
71643Q0 Does this Update warrant updating Any External Parties due to any <b>Terms and Conditional Agreements</b> E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does 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
71643Q1 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. Records of the nature of the nonconformities and any subsequent action taken,	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

including the evaluation,  
any investigation and the rationale for decisions shall be maintained (see 4.2.5)

71643Q2	<p>Viamed Ltd ISO13485:2016 Section: 8.5.1 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? 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> <div></div>	<p>Further Action Required on Issue</p> <div></div>
71643Q3	<p>Viamed Ltd ISO13485:2016 Section: 8.5.2 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"><li>a) reviewing nonconformities (including complaints);</li><li>b) determining the causes of nonconformities;</li><li>c) evaluating the need for action to ensure that nonconformities do not recur;</li><li>d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;</li><li>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;</li><li>f) reviewing the effectiveness of corrective action taken</li></ul> <p>Records of the results of any investigation and action taken shall be maintained (see 4.2.5).</p>	<p>Does Update Affect? Yes ▾</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>Made how to simpler to follow, does not change ISO Procedure as its a how Too</p>	<p>Further Action Required on Issue</p> <div></div>
71643Q4	<p>Viamed Ltd ISO13485:2016 Section: 8.5.3 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"><li>a) determining potential nonconformities and their causes;</li></ul>	<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> <div></div>	<p>Further Action Required on Issue</p> <div></div>

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

71643Q5	<p>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.</p>	<p>Does Update Affect?  <input type="button" value="No"/></p>	<p>Risk Frequency due to Update  <input type="button" value="1.Improbable"/>            Risk Likely Due to Update  <input type="button" value="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>
71643Q6	<p>VST Ltd ISO9001:2015 Section: 7.5.3            Control of documented information</p>	<p>Does Update Affect?  <input type="button" value="No"/></p>	<p>Risk Frequency due to Update  <input type="button" value="1.Improbable"/>            Risk Likely Due to Update  <input type="button" value="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>
71643Q7	<p>VST Ltd ISO9001:2015 Section: 9.1.1            General            The organization shall determine:            a) what needs to be monitored and measured;            b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;            c) when the monitoring and measuring shall be performed;            d) when the results from monitoring and measurement shall be analysed and evaluated.            The organization shall evaluate the performance and the effectiveness of the quality management system.</p>	<p>Does Update Affect?  <input type="button" value="No"/></p>	<p>Risk Frequency due to Update  <input type="button" value="1.Improbable"/>            Risk Likely Due to Update  <input type="button" value="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>

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

71643Q8	<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? <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>
71643Q9	<p>VST Ltd ISO9001:2015 Section: 10.2</p> <p>Nonconformity and corrective action</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>
71643Q10	<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>3) determining if similar nonconformities exist, or could potentially occur;</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>

- 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.

71643Q11 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 Likly Due to Update		
	1.Negligible		
	Action Required:		
	No Action Required		

71643Q12 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 Likly Due to Update		
	2.Minor		
	Action Required:		
	No Action Required		

71643Q13 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 Likly Due to Update		
	1.Negligible		
	Action Required:		
	No Action Required		


71643Q14 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
	1.Improbable		

To Ensure we have the latest version of Med Dev 2.12.  
and update management if its been updated


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

71643Q15  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 Risk Frequency  
Update due to Update  
Affect? 2.Remote ▼  
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

71643Q16  ProcessProcess 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 Risk Frequency  
Update due to Update  
Affect? 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

71643Q17  ProcessProcess 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 Risk Frequency  
Update due to Update  
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

71643Q18  ProcessProcess 7138  
Non Conformance Issues Any New QC21 Forms

Does Risk Frequency  
Update due to Update

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

To review any new QC 21 Forms Current Known Risk potential non conformances go undetected Current Likly 3 Current Frequency 1		Affect? No	1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required		
71643Q19	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 comformances go unfixed 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
71643Q20	Process 7671 Humanmed Non Conformances Humanmed Non Conformances  Current Known Risk non conformations not logged. Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
71643Q21	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	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
71643Q22	Process 7693	Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required

Collect Repair Filing From Warehouse  
Collect the filing form the warehouse  
Current Known Risk paperwork has been missed  
Current Likly 1 Current Frequency 1

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

required

on Issue

71643Q23 ProcessProcess 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 Risk Frequency  
Update due to Update  
Affect? 2.Remote  
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

71643Q24 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 Risk Frequency  
Update due to Update  
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





71643Q25 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 Risk Frequency  
Update due to Update  
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



<p>71643Q26  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 Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>71643Q27  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 Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>71643Q28  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 Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>71643Q29  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 Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

71643Q30  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>
71643Q31  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>
71643Q32  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>
71643Q33  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>

71643Q34	 Process 7857 Software Validation Stock Tracking Check To confirm Software Validation Stock Tracking Check, is functioning as expected Current Known Risk Stock gets mislaid in the warehouse Current Likly 2 Current Frequency 1	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> <div>Risk Likly 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>
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71643Q35	Does Generic CE File Attached to All Technical file #2 Of type 5 require any Notificaions and/or Risk assesment updates due to this update	Does Update Affect? <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>
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71643Q36	Final Notes <div>Made how to simpler to follow, does not change ISO Procedure as its a how Too</div>
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SAVE FORM