

Document QMS Route Map Viamed Ltd ISO13485_2016 Revision ID74847

Suggested Upload Document Name: **Risk Assesment For Updating Document ID74847**

Completed by [Derek Lamb](#) 22 Nov 2021

Reason for Risk Assesment

Route map update only, links all changes together,
see individual VOP for riskRisk Assesment For Updating Document ID74847 anysis of various updates

Document QMS Route Map Viamed Ltd ISO13485_2016 Revision ID74847 Is linked to the Following Standards and processes

Risk Assesment Question ID74847	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
74847Q0 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
74847Q1 Viamed Ltd ISO13485:2016 Section: 4.1 Quality management system	Does Update Affect? Yes ▾	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 Route map update only, links all changes together, see individual VOP for riskRisk Assesment For Updating Document ID74847 anysis of various updates	Further Action Required on Issue
74847Q2 Document ID51629 Audit 01 Picking packing Is Related to this document	Does Update	Risk Frequency due to Update 1.Improbable ▾	Notes On Risk / Benefits statement if required	Further Action Required on Issue

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

74847Q3	Document ID69328 Audit 02 Contract Review and Sales Order Processing 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		

74847Q4	Document ID51631 Audit 03 Design Control 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		

74847Q5	Document ID63821 Audit 04 Accounts and Finance 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		

74847Q6	Document ID69314 Audit 05 Purchasing suppliers 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		

74847Q7 Document ID63048 Audit 06 Calibration 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		

74847Q8 Document ID58347 Audit 07 Handling and Storage 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		

74847Q9 Document ID70147 Audit 08 Training, Competence and Human Resources 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		

74847Q10 Document ID55437 Audit 09 Goods Inward and Product Identity Is Related to

Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required
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this document	Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	required	on Issue
74847Q11 Document ID63807 Audit 10 Documentation Control Is Related to this document	Does 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
74847Q12 Document ID64142 Audit 11 Repairs, Servicing and Returns Is Related to this document	Does 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
74847Q13 Document ID63815 Audit 12 CE Files Is Related to this document	Does 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

74847Q14 Document ID41228 Audit 14 Complaints and Corrective Actions Is Related to this document	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>
74847Q15 Document ID59614 Audit 15 Production Is Related to this document	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>
74847Q16 Document ID69457 Audit 16 Sales and Marketing Is Related to this document	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>
74847Q17 Document ID41240 Audit 17 Internal Audits Is Related to this document	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>

74847Q18 Document ID73320 Audit 18 Management Review Is Related to this document	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>
74847Q19 Document ID68045 Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Is Related to this document	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>
74847Q20 Document ID73324 Audit 20 Process verification to Managment Is Related to this document	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>
74847Q21 Document ID41422 Audit 21 Audit of Audit Is Related to this document	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>

74847Q22 Document ID63052 Audit 22 Post Market Surveillance 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 ▾	<div></div>	<div></div>
	Risk Likly Due to Update		
	1.Negligible ▾		
Action Required:			
No Action Required			

74847Q23 Document ID67997 Audit 23 Analysis of Data 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 ▾	<div></div>	<div></div>
	Risk Likly Due to Update		
	1.Negligible ▾		
Action Required:			
No Action Required			

74847Q24 Document ID68263 Audit 24 Service Logs 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 ▾	<div></div>	<div></div>
	Risk Likly Due to Update		
	1.Negligible ▾		
Action Required:			
No Action Required			

74847Q25 Document ID23221 Audit Schedule 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 ▾	<div></div>	<div></div>
	Risk Likly Due to Update		
	1.Negligible ▾		
Action Required:			
No Action Required			

74847Q26 Final Notes

Route map update only, links all changes together,
see individual VOP for riskRisk Assesment For Updating Document ID74847 anysis of various updates

SAVE FORM