

# Document QMS Route Map Viamed Ltd ISO13485\_2016 Revision ID74166

Suggested Upload Document Name: Risk Assesment For Updating Document ID74166

Completed by Derek Lamb 12 Nov 2021

## Reason for Risk Assesment

BSI Visit monday,  
Pointed out some changes to underlying documentation required

Document QMS Route Map Viamed Ltd ISO13485\_2016 Revision ID74166 Is linked to the Following Standards and processes

| Risk Assesment Question ID74166  | Does Update Risk on Update Affect | Risk Frequency due to Update   | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
|--|-----------------------------------|--|--|----------------------------------|
| 74166Q0 Does this Update warrant updating Any External Parties due to any <b>Terms and Conditional Agreements</b> E.G. Notified Body | Does Update Affect?<br>No         | Risk Frequency due to Update<br>1.Improbable<br>Risk Likly Due to Update<br>1.Negligible<br>Action Required:<br>No Action Required |  |                                  |
| 74166Q1 Viamed Ltd ISO13485:2016 Section: 4.1 Quality management system  | Does Update Affect?<br>Yes        | Risk Frequency due to Update<br>1.Improbable<br>Risk Likly Due to Update<br>1.Negligible<br>Action Required:                       |  |                                  |

No Action  
Required

Documentation updates,  
New Risk assesment linked to  
documentation updates,  
This document in and of itsself is  
simply a route map to the Management  
system

74166Q2 Document ID51629 Audit 01 Picking packing Is  
Related to this document

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

74166Q3 Document ID69328 Audit 02 Contract Review  
and Sales Order Processing Is Related to this  
document

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

74166Q4 Document ID51631 Audit 03 Design Control Is  
Related to this document

Does Risk Frequency  
Update due to Update  
1.Improbable ▼

Affect? Risk Likly Due  
 to Update  
  
Action  
Required:  
No Action  
Required

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74166Q5 Document ID63821 Audit 04 Accounts and Finance Is Related to this document

Does Risk Frequency  
Update due to Update  
Affect?   
 Risk Likly Due  
to Update  
  
Action  
Required:  
No Action  
Required

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74166Q6 Document ID69314 Audit 05 Purchasing suppliers Is Related to this document

Does Risk Frequency  
Update due to Update  
Affect?   
 Risk Likly Due  
to Update  
  
Action  
Required:  
No Action  
Required

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74166Q7 Document ID63048 Audit 06 Calibration Is Related to this document

Does Risk Frequency  
Update due to Update  
Affect?   
 Risk Likly Due  
to Update  
  
Action  
Required:

No Action  
Required

74166Q8 Document ID58347 Audit 07 Handling and Storage Is Related to this document

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

74166Q9 Document ID70147 Audit 08 Training, Competence and Human Resources Is Related to this document

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

74166Q10 Document ID55437 Audit 09 Goods Inward and Product Identity Is Related to this document

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

74166Q11 Document ID63807 Audit 10 Documentation

Does Risk Frequency

Control Is Related to this document

Update due to Update  
Affect? 1.Improbable ▾

No ▾ Risk Likly Due  
to Update

1.Negligible ▾

Action

Required:

No Action

Required

74166Q12 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

74166Q13 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

74166Q14 Document ID41228 Audit 14 Complaints and  
Corrective Actions Is Related to this document

Does Update due to Update  
Affect? 1.Improbable ▾

No ▾ Risk Likly Due  
to Update

Action

1.Negligible ▾

Action  
Required:  
No Action  
Required

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74166Q15 Document ID59614 Audit 15 Production Is  
Related to this document

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾

No ▾

Risk Likly Due  
to Update

1.Negligible ▾

Action  
Required:  
No Action  
Required

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74166Q16 Document ID69457 Audit 16 Sales and  
Marketing Is Related to this document

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾

No ▾

Risk Likly Due  
to Update

1.Negligible ▾

Action  
Required:  
No Action  
Required

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74166Q17 Document ID41240 Audit 17 Internal Audits Is  
Related to this document

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾

No ▾

Risk Likly Due  
to Update

1.Negligible ▾

Action  
Required:  
No Action  
Required

74166Q18 Document ID73320 Audit 18 Management Review Is Related to this document

Does Risk Frequency Update due to Update Affect? 1.Improbable ▾

No ▾ Risk Likly Due to Update 1.Negligible ▾

Action Required: No Action Required

74166Q19 Document ID68045 Audit 19 Health and Safety, Working Conditions and Building Fabric Issues Is Related to this document

Does Risk Frequency Update due to Update Affect? 1.Improbable ▾

No ▾ Risk Likly Due to Update 1.Negligible ▾

Action Required: No Action Required

74166Q20 Document ID73324 Audit 20 Process verification to Management Is Related to this document

Does Risk Frequency Update due to Update Affect? 1.Improbable ▾

No ▾ Risk Likly Due to Update 1.Negligible ▾

Action Required: No Action Required

74166Q21 Document ID41422 Audit 21 Audit of Audit Is Related to this document

Does Risk Frequency Update due to Update 1.Improbable ▾

Affect? Risk Likly Due  
 to Update  
  
Action  
Required:  
No Action  
Required

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74166Q22 Document ID63052 Audit 22 Post Market  
Survellance Is Related to this document

Does Risk Frequency  
Update due to Update  
Affect?   
 Risk Likly Due  
to Update  
  
Action  
Required:  
No Action  
Required

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74166Q23 Document ID67997 Audit 23 Analysis of Data Is  
Related to this document

Does Risk Frequency  
Update due to Update  
Affect?   
 Risk Likly Due  
to Update  
  
Action  
Required:  
No Action  
Required

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74166Q24 Document ID68263 Audit 24 Service Logs Is  
Related to this document

Does Risk Frequency  
Update due to Update  
Affect?   
 Risk Likly Due  
to Update  
  
Action  
Required:



No Action  
Required

74166Q25 Document ID23221 Audit Schedule Is Related to  
this document

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾

No ▾

Risk Likly Due  
to Update

1.Negligible ▾

Action

Required:

No Action

Required

No risks to the underlying system by updating this document

74166Q26 Final Notes