Document QC 21 Non Conformance Revision ID74575

Suggested Upload Document Name: **Risk Assesment For Updating Document ID74575**
Completed by Derek Lamb 11 Nov 2021
Reason for Risk Assesment

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BSI Report 2128198-202111-N4
Added Box to confirm the Corrective action does not affect other parts of the ISO System
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Document QC 21 Non Conformance Revision ID74575 Is linked to the Following Standards and processes

Risk Assesment ID74575	Question	Does Update Affect	Frequency Likly	Severity Likly	Risk Rating	Notes On Risk / Benefits statement if required	Further Action Required on Issue
74575Q0	Does this Update warrant updating Any External Parties due to any **Terms and Conditional Agreements** E.G. Notified Body	No	1.Improbable	1.Negligible	No Action Required		
74575Q1	Viamed Ltd ISO13485:2016 Section: 5.6.2 Review input General The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.	Yes	1.Improbable	1.Negligible	No Action Required	BSI Report 2128198-202111-N4 Added Box to confirm the Corrective action does not affect other parts of the ISO System	
74575Q2	Process7138 Non Conformance Issues Any New QC21 Forms	No	1.Improbable	1.Negligible	No Action Required		

To review any new QC 21 Forms

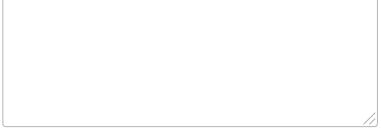|							
74575Q3	🔍Process6931 Customer Complaints Review the Customer Complaints Heading Current Known Risk things are not followed up in a timely manner or are missed Current Likly 4 Current Frequency 1	Yes ▾	1.Improbable ▾	1.Negligible ▾	No Action	BSI Report 2128198-202111-N4 Added Box to confirm the Corrective action does not affect other parts of the ISO System Does not negativly affect Process6931	
74575Q4	🔍Process7070 Management Review To discuss any problems, to assess work load and staffing. To review issues. Current Known Risk Meetings not carried out regularly. Current Likly 2 Current Frequency 1	No ▾	1.Improbable ▾	1.Negligible ▾	No Action Required		
74575Q5	🔍Process7091 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 3 Current Frequency 2	No ▾	1.Improbable ▾	1.Negligible ▾	No Action Required		
74575Q6	🔍Process7713 Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff, Current Known Risk That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Current Likly 2 Current Frequency 2	No ▾	1.Improbable ▾	1.Negligible ▾	No Action Required		

| 74575Q7 | 🔍 Process7741 Review Ethical Policy Review the current Ethical Policy in intrastats Current Known Risk That something is missed that we would like to include Current Likly 1 Current Frequency 1 | No ▾ | 1.Improbable ▾ | 1.Negligible ▾ | No Action Required | | |

74575Q8 🔍 Process7743 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 | No ▾ | 1.Improbable ▾ | 1.Negligible ▾ | No Action Required | | |

74575Q9 🔍 Process7830 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

| | | No ▾ | 1.Improbable ▾ | 1.Negligible ▾ | No Action Required | | |

74575Q10 🔍 Process7837 Review External Parties Influencing The QMS VST / Viamed To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks Current Known Risk External party has un-reviewed expectations Current Likly 1

| | | No ▾ | 1.Improbable ▾ | 1.Negligible ▾ | No Action Required | | |

74575Q11 🔍Process7838
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

No [No ▾] [1.Improbable ▾] [1.Negligible ▾] No Action Required

74575Q12 🔍Process7839
Review VIAMED Feedback - Customer Complaints
To Review Viamed Customer Complaints
Current Known Risk Rolling Issue No Risk
Current Likly 3
Current Frequency 1

[No ▾] [1.Improbable ▾] [1.Negligible ▾] No Action Required

74575Q13 🔍Process7842
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

[No ▾] [1.Improbable ▾] [1.Negligible ▾] No Action Required

74575Q14 🔍Process7846
[No ▾] [1.Improbable ▾] [1.Negligible ▾] No Action Required

ISO System Management Review Viamed
To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13

Current Known Risk Failure to do may cause major non conformites in QMS System
Current Likly 1

| 74575Q15 | 🔍Process7848 Review ISO Scopes
To Review the Scope of the ISO 9001 / ISO 13485 Standards
Current Known Risk No risks Rolling issue to perform task
Current Likly 1
Current Frequency 1 | [No ▾] [1.Improbable ▾] [1.Negligible ▾] | No Action Required | [textarea] | [input] |

| 74575Q16 | 🔍Process7849 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 4
Current Frequency 3 | [No ▾] [1.Improbable ▾] [1.Negligible ▾] | No Action Required | [textarea] | [input] |

| 74575Q17 | 🔍Process7871 Review Exclusion From Viamed 13485:2016 And VST 9001:2015
To review the Exclusions / boundaries to ISO 13485:2016 for Viamed
Current Known Risk Something is missed.
Current Likly 1
Current Frequency 1 | [No ▾] [1.Improbable ▾] [1.Negligible ▾] | No Action Required | [textarea] | [input] |

| 74575Q18 | Final Notes | No ISO Procedures or Process
are negativly affected by updating this document with the new
document proposed |