Document Need Risks and Expectations of External Parties Viamed Revision ID71273

Suggested Upload Document Name: Risk Assesment For Updating Document ID71273

Completed by Derek Lamb 13 Nov 2021

Reason for Risk Assesment Updated the PDF layout from portrait to landscape, changed the overall risk number as per risk definitations to Text output (no action / Risk Benefit / Unacceptable) already in the system. Document Need Risks and Expectations of External Parties Viamed Revision ID71273 Is linked to the Following Standards and processes Risk Does Notes On Risk / Benefits statement if Further Action Required Update Risk on Update **Assesment Question** required on Issue ID71273 Affect 71273Q0 Does this Update warrant updating Any External Risk Fregency Does Parties due to any Terms and Conditional Update due to Update **Agreements** E.G. Notified Body Affect? 1.Improbable ➤ No **v** Risk Likly Due to Update 1.Negligible Action Required: No Action Required 7127301 Viamed Ltd ISO13485:2016 Section: 4.1 Risk Frequency Does Quality management system Update due to Update Affect? 1.Improbable > No **→** Risk Likly Due to Update

1.Negligible

71273Q2 Final Notes

Action Required: No Action Required

No ISO Procedures or Process are negativly affected by updating this document with the new document proposed