Document Structure of the documentation used in the quality management system Revision ID18487

Suggested Upload Document Name: **Risk Assesment For Updating Document ID18487**
Completed by <u>Derek Lamb</u> 21 May 2024
Reason for Risk Assesment

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added vop, and added routemap to the structure
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Document Structure of the documentation used in the quality management system Revision ID18487 Is linked to the Following Standards and processes

Risk Assesment Question ID18487		Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required
18487Q0	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 Freqency due to Update 1.Improbable ⌄ Risk Likly Due to Update 1.Negligible ⌄ Action Required: No Action Required	Notes On Risk / Benefits statement if required
18487Q1	Viamed Ltd ISO13485:2016 Section: 4.2.2 Documentation requirements The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	Does Update Affect? No ⌄	Risk Freqency due to Update 1.Improbable ⌄ Risk Likly Due to Update 1.Negligible ⌄ Action Required: No Action Required	Notes On Risk / Benefits statement if required `updated structure does not aff ISO`
18487Q2	Final Notes			

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