## Document VM3COP00.00 VOP00.00 VST Quality Statement policy and objectives Revision ID22062

Suggested Upload Document Name: **Risk Assesment For Updating Document ID22062** Completed by <u>Derek Lamb</u> 08 Oct 2024

	Reason for Risk Assesment						
343195 ISO standards been amended this is the first step in meeting the new objective							
Document Risk Assesmen ID22062	VM3COP00.00 VOP00.00 VST Quality Statement policy and objectives Revision ID:	22062 Is l Does Update Affect	inked to the Following Risk on Update	s Standards and processes  Notes On Risk / Benefits statement is required			
22062Q0	Does this Update warrant updating Any External Parties due to any <b>Terms and Conditional Agreements</b> E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does O 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 i required			
22062Q1	Viamed Ltd ISO13485:2016 Section: 4.2.1 Documentation requirements The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	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 i required			
22062Q2	Viamed Ltd ISO13485:2016 Section: 5.3  Quality policy  Top management shall ensure that the quality policy: a) is applicable to the purpose of the organization; b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; c) provides a framework for establishing and reviewing quality objectives; d) is communicated and understood within the organization; e) is reviewed for continuing suitability.	Does Update Affect?	Risk Frequency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement i required			
22062Q3	Viamed Ltd ISO13485:2016 Section: 5.4.2 Quality management system planning Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	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 is required			
22062Q4	VST Ltd ISO9001:2015 Section: 4 Context of the organization	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 required see issue 343195 for action updated the objectives overviwith new standard amendment			
22062Q5	VST Ltd ISO9001:2015 Section: 5.1.1  General  Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes:	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 is required			

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1.Negligible 
Action Required:
No Action Required

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brought to light that was better not addressed.

Current Likly 1 Current Frequency 1

T I: C	Process 7848 Review ISO Scopes To Review the Scope of the SO 9001 / ISO 13485 Standards Current Known Risk No risks Rolling issue to perform task Current Likly 1 Current Frequency 1	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
R C n	Process 7849 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 1 Current Frequency 3	Does Update Affect?	Risk Freqency due to Update 3.0ccasional  Risk Likly Due to Update 1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required
T	Process 7953 Vandagraph Delivery Notifications To Send Vandagraph Delivery notifications Current Known Risk task not carried out Current Likly 1 Current Frequency 1	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
S	Process 8029 Send Intercompany Invoices To Jean Send Inter Company Invoices to Jean. Download from sales page and email. Current Known Risk that invoice will be missed Current Likly 1 Current Frequency 1	Does Update Affect?	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
	Pinal Notes  No ISO Procedures or Process  are negativly affected by updating this document with the new docum	nent prop		

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