

Document VM3COP40.47 Vandagraph Expedition sensor conversion R-22AEX 0110227 Revision ID9430

Suggested Upload Document Name: **Risk Assesment For Updating Document ID9430**

Completed by [Derek Lamb](#) 21 Apr 2022

Reason for Risk Assesment

change of part numbers

Document VM3COP40.47 Vandagraph Expedition sensor conversion R-22AEX 0110227 Revision ID9430 Is linked to the Following Standards and processes

Risk Assesment Question ID9430	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement required
9430Q0 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 Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q1 Viamed Ltd ISO13485:2016 Section: 7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q2 Viamed Ltd ISO13485:2016 Section: 7.5.1 Control of production and service provision Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q3 Viamed Ltd ISO13485:2016 Section: 8.3.4 Rework The organization shall perform rework in accordance with documented procedures that takes into	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due	Notes On Risk / Benefits statement required

account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained (see 4.2.5).

to Update

1.Negligible ▼

Action









Required:

No Action

Required

9430Q4	<p>VST Ltd ISO9001:2015 Section: 8.1 Operational planning and control The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:</p> <ol style="list-style-type: none"> determining the requirements for the products and services; establishing criteria for: <ol style="list-style-type: none"> the processes; the acceptance of products and services; determining the resources needed to achieve conformity to the product and service requirements; implementing control of the processes in accordance with the criteria; determining, maintaining and retaining documented information to the extent necessary: <ol style="list-style-type: none"> to have confidence that the processes have been carried out as planned; to demonstrate the conformity of products and services to their requirements. <p>The output of this planning shall be suitable for the organizations operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4).</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼ Risk Likely Due to Update 1.Negligible ▼ Action Required: No Action Required</p>	Notes On Risk / Benefits statement required
9430Q5	<p>VST Ltd ISO9001:2015 Section: 8.5.1 Control of production and service provision The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:</p> <ol style="list-style-type: none"> the availability of documented information that defines: <ol style="list-style-type: none"> the characteristics of the products to be produced, the services to be provided, or the activities to be performed; the results to be achieved; the availability and use of suitable monitoring and measuring resources; the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; the use of suitable infrastructure and environment for the operation of processes; the appointment of competent persons, including any required qualification; the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; the implementation of actions to prevent human error; the implementation of release, delivery and post-delivery activities 	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼ Risk Likely Due to Update 1.Negligible ▼ Action Required: No Action Required</p>	Notes On Risk / Benefits statement required
9430Q6	<p>Process7736 Production Start Job List When a new production is needed we the production job to the list of procedures. Check to make sure that every new job has a procedure linked to it.</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 2.Remote ▼ Risk Likely Due to Update 2.Minor ▼ Action Required: No Action Required</p>	Notes On Risk / Benefits statement required
9430Q7	<p>Process7737 Production In Production List Review the Production List, check and list those items that were started more than 30 days ago have not been through QA. Audit is carried out and production is reviewed and chased at this point.</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 2.Remote ▼ Risk Likely Due to Update 2.Minor ▼ Action Required: No Action Required</p>	Notes On Risk / Benefits statement required
9430Q8	<p>Process7738 Production Statistics Production Review, Identify any production jobs taking a long amount of time</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update 1.Improbable ▼ Risk Likely Due to Update</p>	Notes On Risk / Benefits statement required

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			Action	
			Required:	
			No Action	
			Required	
9430Q9	Process8000 Verification Production Paperwork Verify all production jobs have correct paperwork in the ducket with the production job	Does Update Affect? No Risk Frequency due to Update Risk Likly Due to Update Action Required: No Action Required		Notes On Risk / Benefits statement required
9430Q10	ProcessProcess 5858 Opera Stock Adjustments Opera Counts bulk stock in and issues stock out against orders. Multiple processes cause stock to be used internally, Opera requires a weekly update to bring the stock count into line with whats been used outside the invoicing systems NO LONGER REQUIRED, New system live counts these now Current Known Risk Stock valuations will get inaccurate if the process is not performed. Current Likly 2 Current Frequency 1	Does Update Affect? No Risk Frequency due to Update Risk Likly Due to Update Action Required: No Action Required	1.Improbable 2.Minor	Notes On Risk / Benefits statement required
9430Q11	ProcessProcess 5935 Stock Allocations To allocate stock that has not automatically be linked to a repair or invoice. Current Known Risk Items that should be linked to a invoice are not in the allocations list. That items are allocated incorrectly on the list. Current Likly 2 Current Frequency 1	Does Update Affect? No Risk Frequency due to Update Risk Likly Due to Update Action Required: No Action Required	1.Improbable 2.Minor	Notes On Risk / Benefits statement required
9430Q12	ProcessProcess 6838 Opera Negative Stock To find and correct opera when it reads Negative stock values. NOT REQUIRED ANYMORE Opera Current Known Risk Damage Opera. Current Likly 1 Current Frequency 1	Does Update Affect? No Risk Frequency due to Update Risk Likly Due to Update Action Required: No Action Required	1.Improbable 1.Negligible	Notes On Risk / Benefits statement required
9430Q13	ProcessProcess 6850 Current Stock Levels Review current stock levels Current Known Risk If the levels are incorrect or we have a shortages then customers will not receive their goods in a timely manor. Current Likly 2 Current Frequency 1	Does Update Affect? No Risk Frequency due to Update Risk Likly Due to Update Action Required: No Action Required	1.Improbable 2.Minor	Notes On Risk / Benefits statement required
9430Q14	ProcessProcess 6945 Missing Stock or Adjustments To synchronise Opera stock Count against Intrastats internal movement of stock, E.G. Items that wont uniquely appear on an opera order - such as production parts. TASK IS NO LONGER REQUIRED Current Known Risk Opera and Intrastats go out of sync Current Likly 1 Current Frequency 1	Does Update Affect? No Risk Frequency due to Update Risk Likly Due to Update Action Required: No Action Required	1.Improbable 1.Negligible	Notes On Risk / Benefits statement required
9430Q15	ProcessProcess 6955 Production Requirements To set production job for any stock item that is needed for customer back order, warehouse requests or marketing Current Known Risk that jobs will not be added and customers orders will be delayed Current Likly 2 Current Frequency 1	Does Update Affect? No Risk Frequency due to Update Risk Likly Due to Update Action Required:	1.Improbable 2.Minor	Notes On Risk / Benefits statement required

		No Action Required	
9430Q16	 Process 7048 Control of monitoring and measuring devices Control of monitoring and measuring devices Current Known Risk that equipment will be missed Current Likly 1 Current Frequency 2	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="2.Remote"/> Frequency due to Update <input type="button" value="1.Negligible"/> Risk Likely Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q17	 Process 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates. Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="2.Remote"/> Frequency due to Update <input type="button" value="1.Negligible"/> Risk Likely Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q18	 Process 7679 Check Stock Requirements Supplier Teledyne To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency due to Update <input type="button" value="2.Minor"/> Risk Likely Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q19	 Process 7680 Check Stock Requirements Supplier Envitec To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency due to Update <input type="button" value="2.Minor"/> Risk Likely Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q20	 Process 7681 Check Stock Requirements Supplier Posey To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency due to Update <input type="button" value="2.Minor"/> Risk Likely Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q21	 Process 7682 Check Stock Requirements Supplier Blueprint To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency due to Update <input type="button" value="2.Minor"/> Risk Likely Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q22	 Process 7689 Move Stock From QA Shelf To Stock Shelf Monday Move Stock From QA Shelf To Stock Shelf Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency due to Update <input type="button" value="2.Minor"/> Risk Likely Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required
9430Q23	 Process 7694 Move Stock From QA Shelf To Stock Shelf Tuesday	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency due to Update <input type="button" value="2.Minor"/> Risk Likely Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement required

Move Stock From QA Shelf To Stock Shelf

Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. The stock is not on the correct shelf.

Current Likly 2 Current Frequency 1

Affect?