

Document VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection Revision ID227125

Suggested Upload Document Name: **Risk Assessment For Updating Document ID227125**

Completed by [Derek Lamb](#) 24 Jul 2026

Reason for Risk Assessment

VOP 05 has been reviewed, updated and reissued under document reference 403869.17066. The procedure continues to control supplier approval, supplier monitoring, purchase orders, incoming goods, rejected goods and supplier returns. The revision clarifies current working practices and strengthens the documented supplier risk and Modern Slavery review requirements. The update does not remove any existing quality controls or reduce the level of supplier oversight.

Document VOP 05 Supplier Control, Supplier Review, Purchase Orders, Supplier Returns and Rejection Revision ID227125 Is linked to the Following Standards and processes

Risk Assessment ID227125	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required
227125Q0	Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significant 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 if required
227125Q1	Viamed Ltd ISO13485:2016 Section: 4.1.5 Quality management system For each quality management system process, the organization shall: When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.	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 if required
227125Q2	Viamed Ltd ISO13485:2016 Section: 6.4.2 Contamination control As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.	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 if required
227125Q3	Viamed Ltd ISO13485:2016 Section: 7.4.1 Purchasing process The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a) based on the supplier's ability to provide product that meets the organizations' requirements; b) based on the performance of the supplier; c) based on the effect of the purchased product on the quality of the medical device; d) proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).	Does Update Affect? Yes ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likely Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required delivery, certification and performance controls remain unchanged. The update therefore improves documented supplier oversight without reducing existing purchasing controls.

227125Q4	Viamed Ltd ISO13485:2016 Section: 7.4.2 Purchasing information Purchasing information shall describe or reference the product to be purchased, including as appropriate: a) product specifications; b) requirements for product acceptance, procedures, processes and equipment; c) requirements for qualification of supplier personnel; d) quality management system requirements. The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).	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 i required
227125Q5	Viamed Ltd ISO13485:2016 Section: 8.4 Analysis of data The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).	Does Update Affect? Yes ▾	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 and management review. This provides additional documente evidence for the analysis of supplier data and does not remove or weaken any existing data-monitoring requirements.
227125Q6	VST Ltd ISO9001:2015+A1 Section: 8.4.1 General The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.	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 i required
227125Q7	VST Ltd ISO9001:2015+A1 Section: 8.4.2 Type and extent of control The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall: a) ensure that externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration:	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 i required

- 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
- 2) the effectiveness of the controls applied by the external provider;
- d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

227125Q8	VST Ltd ISO9001:2015+A1 Section: 8.4.3 Information for external providers The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for: a) the processes, products and services to be provided; b) the approval of: 1) products and services; 2) methods, processes and equipment; 3) the release of products and services; c) competence, including any required qualification of persons; d) the external providers' interactions with the organization; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	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 i required
227125Q9	VST Ltd ISO9001:2015+A1 Section: 9.1.3 Analysis and evaluation The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. NOTE Methods to analyse data can include statistical techniques.	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 i required
227125Q10 28	Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.	Does Update Affect? Yes	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 including consideration of Modern Slavery and ethical sourcing risks. Existing chec of ISO certification, supplie performance and internal grad remain in place.
227125Q11 7784	Check Returns Supplier Envitec Supplier returns to Envitec, return any products waiting to be returned	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q12 7785	Check Returns Supplier Teledyne Supplier returns to Teledyne, return any products waiting to be returned	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q13 7786	Check Returns Supplier Maxtec Supplier returns to Maxtec, return any products waiting to be returned	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q14 7787	Check Returns All Supplier Review the returns that are present in the duckets, for each supplier as per the issues.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable	Notes On Risk / Benefits statement i required

		Affect? No ▾	Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	
227125Q15 6972	UPS Shipping Fuel Surcharge task no longer required, WE switched touns online WITH LIVE PRICES Update the UPS rates to ensure we charge the correct amount of carriage	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q16 7975	Arrange Teledyne Returns Arranging Teledyne failed sensors for credits and / or return. Teledyne do not want us to return Medical Sensors that have been sent out to the customer and then failed. They will be crediting these without us sending back Automotive sensors are not to be returned either and will be credited unseen.	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 i required
227125Q17 7984	Check For Viking Invoices Check the Viking Web site for invoices. As they only come in to Info@viamed.co.uk and not to accounts.	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 i required
227125Q18 8009	Verification Stock Items And Locations Randomly test/list 5 stock Items from finished shelves. to verify their loction in intrastats, Check for Barcode label. check serial number or batchnumber where applicable to the barcode. confirm packaged suitably.	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 i required
227125Q19 7991	Verification Purchasing Documentation Verification of our purchasing documents.	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q20 8002	Verification Todays Goods In Verification goods in products correctly identified	Does Update Affect? No ▾	Risk Frequency due to Update 3.Occasional ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q21 8003	Verification Supplier Delivery Notes Verify the supplier delivery notes to the ordering documents and goods in deliveries is being done correctly	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q22 8030	Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required

227125Q23 8034	Purchase Order Invoice Review Stage 2 Stage 2 of checking supplier prices against our Purchase orders.	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q24 8039	Weee Report Due Vandagraph Annual Weee Report Due Vandagraph Annual	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 i required
227125Q25 8040	Weee Report Due Vandagraph Qtr Weee Report Due Vandagraph Qtr	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 i required
227125Q26 8052	Check Supplier Returns Check Supplier returns for items not received back	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q27 8051	Purchase Order Log Viamed Purchase Order log Viamed ensure the purchase order log is up to date	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 i required
227125Q28 Process 39	Enviromental Policy Document Review Ensure our Viamed Environment and WEEE Polycys are upto date and suitable for current legislation Current Known Risk Potential to break the Law of the land with unsuitable polycys Current Likly 1 Current Frequency 2	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q29 Process 7826	Goods In Processes To Receive Goods from Suppliers Current Known Risk incorrectly booked in not booked in Current Likly 2 Current Frequency 2	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q30 Process 7799	Opera Purchase Ledger Close The closing down of the previous months purchase ledger for accounts purposes. Current Known Risk The system crashes, invoices could be missed. Current Likly 1 Current Frequency 2	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q31 Process 7755	Fast Hosts Invoice To Send Invoices for online services to Helen every 12 months on the issue Current Known Risk No risks to system. Accounting excersise Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required

227125Q32	Process 7701 AWS Amazon Web Services Amazon Web Services, is an online service, which basically simply provides a Linux PC out on the Web. Viamed uses this, for Web development of Websites: It hosts a working backup of many websites. Viamed / vst / vandagraph etc.. Current Known Risk No risks as its used for development and backups of working websites Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q33	Process 7700 Domain Name Management Maintain Domains for websites Current Known Risk Loss of website presense Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q34	Process 7751 VST Purchase Order Log Check the VST PO log is up to date with confirmations and expected shipping dates Current Known Risk The order is not checked and the supplier has not received it ergo we do not receive the order Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q35	Process 7823 Saftey Tester Data Backup the Fluke ESA615 Safety tester CE Copy any files to the Z Drive - safety tester backupdata Current Known Risk That this will not be carried out. Current Likly 1 Current Frequency 1	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 i required
227125Q36	Process 7787 Check Returns All Supplier Review the returns that are present in the duckets, for each supplier as per the issues. Current Known Risk Goods not returned in a timely manor so causing items to be out of warranty. Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q37	Process 7786 Check Returns Supplier Maxtec Supplier returns to Maxtec, return any products waiting to be returned Current Known Risk Product not returned, risks not analysed Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q38	Process 7785 Check Returns Supplier Teledyne Supplier returns to Teledyne, return any products waiting to be returned Current Known Risk Product not returned, risks not analysed Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q39	Process 7784 Check Returns Supplier Envitec Supplier returns to Envitec, return any products waiting to be returned Current Known Risk Product not returned so missing the supplier warranty Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q40	Process 7830 Review Q.A. Failures Report To review the Quantities of Failed product per Stock reference Passing through the Q.A. system Current Known Risk That a high proportion of a product might fail QA and not be flagged Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required

227125Q41	Process 7822 Review Oxylink Stock To check we have the stock available to supply our customer Oxylink. NOTE THIS PROCESS HAS BEEN STOPPED. Part number has been superseded Current Known Risk The we do not have the stock needed to satisfy the orders for this customer. Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q42	Process 27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits Current Known Risk that the task is missed that follow ups are missed Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q43	Process 7834 Financial Review The review the Financial requirements Current Known Risk Non Current Likly 1 Current Frequency 1	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 i required
227125Q44	Process 26 Company Resources Overview of the Company using various data Reporting Screens Current Known Risk Not enough resources to complete tasks Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q45	Process 7713 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	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q46	Process 7837 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 Current Frequency 1	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 i required
227125Q47	Process 7840 Review VST Feedback - Customer Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised Current Known Risk That an issue or report might be missed. That a Negative feedback form Products might not be reviewed Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q48	Process 7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised Current Known Risk things are not followed up in a timely manner or are missed Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q49	Process 7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise Current Known Risk Issues could be missed Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required:	Notes On Risk / Benefits statement i required

No Action Required

227125Q50	Process 7846 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 Current Frequency 1	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 i required
227125Q51	Process 7848 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	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 i required
227125Q52	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? No	Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q53	Process 7871 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	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 i required
227125Q54	Process 7876 Maintain Update Of ISO Route Maps To review Route map VIAMED 13485:2016 and VST 9001:2015 See if a new Summary sheet needs producing, print new PDF, and upload on top of the old summary Current Known Risk Summary sheet gets out of date. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q55	Process 7878 Review Possible Upcoming Regulation Changes Review possible legal / regulator changes that might affect Viamed / VST Current Known Risk Legal / Regulatory changes stop us being able to carry out our processes as per QMS Current Likly 1 Current Frequency 3	Does Update Affect? No	Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q56	Process 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading. Current Known Risk Supplier certificates go out of date, or they lose ISO standards and we're unaware Current Likly 1 Current Frequency 1	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 i required
227125Q57	Process 5889 Audit And Task - Audit To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits Current Known Risk non risk to process, Risk of not completing is Jobs / tasks can go not done Current Likly 4 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q58	Process 7071 Post Market Surveillance The process by which re view and risk assess all product files, check that no	Does Update 	Risk Frequency due to Update 3.Occasional	Notes On Risk / Benefits statement i required

	Products / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.	Affect? No ▾	Risk Likely Due to Update 1.Negligible ▾ Action Required: No Action Required	
	Current Known Risk Loss of certifications Unforeseen product risks. Current Likly 1 Current Frequency 3			
227125Q59	Process 7199 Non Conformities Review Viamed To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement. Current Known Risk Non conformances go unfixed Current Likly 2 Current Frequency 2	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likely Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q60	Process 7743 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	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likely Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q61	Process 7827 Review The Quality Policy VST To review the Quality policy and check it is still valid and upto date. Current Known Risk that policy will go out of date Current Likly 1 Current Frequency 1	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 i required
227125Q62	Process 7833 Importance Of Effective Quality Management To Remind Staff of the Importance of the ISO systems and they should be following the procedures Current Known Risk people may become careless Current Likly 2 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likely Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q63	Process 6829 Supplier Review - Outstanding orders Orders that have not been supplied in the time scale provided. Current Known Risk That good will be delayed and therefore not available to customers. Current Likly 2 Current Frequency 2	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likely Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q64	Process 6832 Supplier Review Future orders Orders that will be placed in the future. Current Known Risk That we will not place the correct orders and the right time. Current Likly 2 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likely Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q65	Process 7091 Calibration Index To ensure that all equipment that requires calibration is done. In the correct timescale and manor. Make sure all equipment has a date of calibration on it Current Known Risk That equipment we use to may not be calibrated when we need it. Or the date may not be attached. Current Likly 1 Current Frequency 2	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likely Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q66	Process 5881 Training Records Review Keep Staff Training records upto date See if any records need updating, also see if any records need signing off Current Known Risk Keep enough trained staff to perform our tasks Current Likly 2 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likely Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required

227125Q67	Process 7847 Health And Safety Review Perform HSE Risk Assessment, Re issue Message of the Day or send company issue with regard to Employees being aware of HSE documentation / policy. and Location of Fire Exits and First Aid Kits. Send new Issue to Projects Asking if New HSE implications have arisen from new products. Review Online the Local Community Risk Register. Check the Viamed Overall Risk Analysis Program Document in the Index to check its still current. Check the health and safety signage Current Known Risk HSE Risks to Staff and business Current Likly 1 Current Frequency 1	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 i required
227125Q68	Process 7793 Team Review Meeting Duplicate Issue needs process removing see processid 7750 Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1	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 i required
227125Q69	Process 7707 Send Purchase Orders To Suppliers Emailing purchase orders to suppliers Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1	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 i required
227125Q70	Process 5868 Return Goods To Suppliers To get Returns numbers from suppliers with return shipments pending. Current Known Risk Not performing the process can lead to products being returned within the warranty period causing financial loss. Current Likly 2 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q71	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? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q72	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? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q73	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? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q74	Process 7682 Check Stock Requirements Supplier Bluepoint 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? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required

227125Q75	Process 7683 Check Stock For Proforma To check that we have stock in for customer proformas. 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? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q76	Process 7923 Review Of Credits Received From Suppliers To Review and tidy up any outstanding RMAs that have been resolved by Supplier credit notes Current Known Risk credits missed or not received Current Likly 1 Current Frequency 1	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 i required
227125Q77	Process 6819 Supplier Payments and Invoice processing Inputting the invoices from suppliers for the correct month. Ensuring they are all entered in to the correct period. Current Known Risk invoices missed and therefore absent from accounts and Vat return Current Likly 1 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q78	Process 7882 Purchase Payments Pay suppliers within terms Current Known Risk pay the wrong amount or to the wrong company. Not pay in terms Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q79	Process 7933 Purchasing Invoice Processing Inputting the invoices from suppliers for the correct month. Ensuring they are all entered in to the correct period. Current Known Risk invoices missed and therefore absent from accounts and Vat return Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q80	Process 5855 Purchase Order Requirements Teledyne To contact Teledyne and confirm the purchase orders we have outstanding for them Current Known Risk That good that are required will not be available. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q81	Process 8025 Check We Do Not Require A EU European Representatives Review the below statement and make sure it is still valid and correct. `Viamed Group of companies does not involve the large-scale use of special category or criminal offence data. We also only occasionally process low risk data of individuals in the EU. We do not need to appoint a EU European representatives.` With this in mind we have reasoned we are not required to appoint any EU European representatives in EU member states. Current Known Risk that we may miss something or find we have made a wrong decision Current Likly 1 Current Frequency 3	Does Update Affect? No	Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q82	Process 8026 Automotive Competitor Price Review To review competitor automotive prices Current Known Risk That we may miss a event that has caused a large increase or decrease in competitor prices. Current Likly 1 Current Frequency 1	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 i required
227125Q83	Process 8030 Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier Current Known Risk We over pay for products or services Current Likly 1 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update	Notes On Risk / Benefits statement i required

			1.Negligible ▾ Action Required: No Action Required	
227125Q84	Process 8085 Stock Figure - Correct Xero To Intrastats To correct the stock in the accounts package so it matches what we have in the building and on Intrastats. So the figures are correct and we can get a better idea of where we are with finances Current Known Risk That the figure is incorrect The journal in xero is incorrect Current Likly 1 Current Frequency 1	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 i required
227125Q85	Process 8101 Intercompany Admin Orders Processed To make sure the inter company orders / Admin fee are processed between Viamed and Vandagraph and viamed and VST. Current Known Risk Risk are the orders not being generated and invoice not being invoiced. Current Likly 2 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q86	Process 7798 Operational Throughput, Fulfilment and Dispatch Performance Review Review monthly operational throughput, fulfilment performance, staffing capacity, dispatch responsiveness, operational quality indicators, courier usage and historical operational trends to support management review, operational planning and continuous improvement. Current Known Risk Risks include: - Incorrect operational reporting - Line-level fulfilment visibility limitations - Supplier delays incorrectly inflating late shipment metrics - Operational dependency on key staff - Incorrect data interpretation - Failure to identify operational trends - Courier dependency - Incomplete monthly reporting Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q87	Process 5895 Completing Office Job List Ensuring that the allocated tasks are being completed Current Known Risk Office staff are too busy Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
227125Q88	Process 8103 Managing Director Responsibilitys Review New Process as of 14 / 05 / 2026. Roles Titles Processes and Procedures ADMIN End column Management Review, Print to PDF, Find the previous months report, send both via AI to summarise progress. To provide a structured, top-down review of the Managing Director role and the processes assigned to it. The review considers whether management responsibilities remain correctly allocated, whether the associated processes continue to operate effectively, and whether significant weaknesses, overdue activities, resource limitations, missing controls or adverse trends require management action. This review does not repeat the detailed investigation or closure review of individual issues. Individual issues are reviewed through their normal operational, investigation, audit and final closure processes. The purpose of this process is to assess the overall effectiveness, control and suitability of the management system from the Managing Director level. Current Known Risk The review may become a box-ticking exercise without meaningful consideration of the overall management system. The large number of linked processes may make significant exceptions difficult to identify.	Does Update Affect? No ▾	Risk Frequency due to Update 3.Occasional ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required

Excessive reliance on one individual may create a management and business-continuity risk.

Responsibility records may show employees as trained or assigned without sufficient practical backup capability.

Missing audits, objectives or risk assessments may be accepted without an appropriate management decision.

Individual issues may be reviewed repeatedly while wider trends or systemic weaknesses are overlooked.

Actions identified during the review may not be separately recorded, allocated or followed through.

Current Likly 2 Current Frequency 3

227125Q89	Process 8105 Documentation And Records Controller Review New Process as of 14 / 05 / 2026. Roles Titles Processes and Procedures ADMIN Viamed End column of Documentation And Records Controller Responsibilitys Review Print to PDF, To provide a structured, top-down review of the responsibilities and processes assigned to the Documentation and Records Controller. The review considers whether documents and records remain current, identifiable, approved, accessible, secure, retrievable and protected against unintended alteration or loss. It includes oversight of the Document Index, document review dates, duplicate documents, obsolete documents, staff access permissions, controlled forms, supporting records, external documents and retention arrangements. This review does not repeat every individual document check or issue closure. Those activities are completed through their normal rolling tasks, audits and document-control processes. The purpose of this review is to identify wider weaknesses, overdue controls, access concerns, missing records and systemic documentation risks. Current Known Risk Obsolete or incorrect documents may remain available for use. Required records may be missing, incomplete, incorrectly filed or difficult to retrieve. Staff may retain access to sensitive information that is no longer required for their role. Required users may not have access to the current approved version of a document. Duplicate documents may create uncertainty over which version is authoritative. Review dates or expiry dates may be missed. Records may be lost, damaged or become inaccessible because of system failure or inadequate backup arrangements. Excessive reliance on Derek and Helen may create a continuity and knowledge risk. The review may focus on administrative completeness without checking whether staff actually use the correct documents. Significant document-control weaknesses may be noted but not converted into traceable corrective actions. Current Likly 2 Current Frequency 4	Does Update Affect? No	Risk Frequency due to Update 4.Probable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
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227125Q90	Does Generic CE File Attached to All Technical file #2 Of type 5 require any Notificaions and/or Risk assesment updates due to this update	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 i required
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227125Q91	Final Notes No ISO Procedures or Process are negatively affected by updating this document with the new document proposed
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SAVE FORM Only saves your progress in filling in above Questions - No feed back to pressing save form button
Once Form Complete Print Page to PDF (Landscape mode prefereable), go back to document upload page and upload to risk assesment button