

Document VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records Revision ID75407

Suggested Upload Document Name: **Risk Assessment For Updating Document ID75407**

Completed by [Derek Lamb](#) 01 Jun 2023

Reason for Risk Assessment

added processes and process control to document,

Document VOP 01 Documentation and Records, Control, Creation, Storage, Retrieval, Revision Control and Online Records Revision ID75407 Is linked to the Following Standards and processes

Risk Assessment ID75407	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q0	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 Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q1	Viamed Ltd ISO13485:2016 Section: 4.1.1 Quality management system The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.	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 if required	Further Action Required on Issue
75407Q2	Viamed Ltd ISO13485:2016 Section: 4.1.4 Quality management system For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.	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 if required	Further Action Required on Issue
75407Q3	Viamed Ltd ISO13485:2016 Section: 4.2 Documentation requirements	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 if required	Further Action Required on Issue
75407Q4	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 Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q5	Viamed Ltd ISO13485:2016 Section: 4.2.4 Control of documents Documentation requirements Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5. A documented procedure shall define the controls needed to: a) review and approve documents for adequacy prior to issue; b) review, update as necessary and re-approve documents; c) ensure that the current revision status of and changes to documents are identified; d) ensure that relevant versions of applicable documents are available at points of use; e) ensure that documents remain legible and readily identifiable; f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled; g) prevent deterioration or loss of documents; h) prevent the unintended use of obsolete documents and apply suitable identification to them. The organization shall ensure that changes to documents are reviewed and approved	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 if required	Further Action Required on Issue

either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable

75407Q6	Viamed Ltd ISO13485:2016 Section: 4.2.5 Control of records Documentation requirements Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements. Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable. The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.	Does Update Affect? No v	Risk Frequency due to Update 1.Improbable v Risk Likly Due to Update 1.Negligible v Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q7	VST Ltd ISO9001:2015 Section: 4.3 Determining the scope of the quality management system The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.	Does Update Affect? No v	Risk Frequency due to Update 1.Improbable v Risk Likly Due to Update 1.Negligible v Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q8	VST Ltd ISO9001:2015 Section: 4.4.2 Quality management system and its processes To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned.	Does Update Affect? No v	Risk Frequency due to Update 1.Improbable v Risk Likly Due to Update 1.Negligible v Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q9	VST Ltd ISO9001:2015 Section: 5.2.2 Communicating the quality policy The quality policy shall: a) be available and be maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as appropriate.	Does Update Affect? No v	Risk Frequency due to Update 1.Improbable v Risk Likly Due to Update 1.Negligible v Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q10	VST Ltd ISO9001:2015 Section: 6.3 Planning of changes When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities.	Does Update Affect? No v	Risk Frequency due to Update 1.Improbable v Risk Likly Due to Update 1.Negligible v Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q11	VST Ltd ISO9001:2015 Section: 7.5.1 General 7.5.1 General The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management system can differ from one organization to another due to: ◆◆◆◆ the size of organization and its type of activities, processes, products and services; ◆◆◆◆ the complexity of processes and their interactions; ◆ the competence of persons.	Does Update Affect? No v	Risk Frequency due to Update 1.Improbable v Risk Likly Due to Update 1.Negligible v Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

75407Q12	VST Ltd ISO9001:2015 Section: 7.5.2 Creating and updating 7.5.2 Creating and updating When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy.	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	Further Action Required on Issue
75407Q13	VST Ltd ISO9001:2015 Section: 7.5.3 Control of documented information	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	Further Action Required on Issue
75407Q14	VST Ltd ISO9001:2015 Section: 8.2.3.2 The organization shall retain documented information, as applicable: a) on the results of the review; b) on any new requirements for the products and services.	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	Further Action Required on Issue
75407Q15	VST Ltd ISO9001:2015 Section: 8.2.4 Changes to requirements for products and services The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	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	Further Action Required on Issue
75407Q16	59 Out Of Date Documents Check the Document Index for any out of date documents,	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q17	5851 Duplicate Documents Removal of Duplicate documents	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q18	5940 Thumb Nail Processor Generate the Thumbs nails for the document Index	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 if required	Further Action Required on Issue
75407Q19	7130 Intrastats Information for Intrastats and L Drive To Review the L Drive Library is in sync with Intrastats Documentation TASK DISCONTIUNED, L Drive has been replaced with Intrastats	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q20	5890 Check Website ISO Documents Ensure the online available copies of our ISO standards are upto date	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q21	7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products In order to sell in the USA / Canada Markets products need to be registered with the FDA.	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	Further Action Required on Issue
75407Q22	7827 Review The Quality Policy VST To review the Quality policy and check it is still valid and upto date.	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	Further Action Required on Issue

75407Q23	7828 Review The Quality Policy Viamed To review the Quality policy and check it is still valid and upto 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 if required 	Further Action Required on Issue
75407Q24	5934 Staff Training To check that any training that has been done is valid and then checked off the training record. Including enough detail to describe what has been coved in the training and any material used.	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 if required 	Further Action Required on Issue
75407Q25	7941 Check Leaflets, Letterhead And Other Paperwork To See If The Correct BSI Logo Is In Use. Remove All Old If Found. Check Leaflets, Letterhead and other paperwork to see if the correct BSI logo is in use. Remove and dispose of all old items if found. Ask Catrin to review the website for old leaflets.	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 if required 	Further Action Required on Issue
75407Q26	7987 Sync External Telephone Logs To Export Telephone logs from the phone system to intrastats	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 if required 	Further Action Required on Issue
75407Q27	7992 COSHH Datasheet Reminders Remind staff to supply any new coshh and or datasheet to technical manager to be added to the system.	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 if required 	Further Action Required on Issue
75407Q28	8001 Verification Stock Linked To Documents Verify stock is being linked to documents when required	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 if required 	Further Action Required on Issue
75407Q29	Process 9 Distribution Of Faxes Distribute recieved faxes Current Known Risk lost faxes 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 if required 	Further Action Required on Issue
75407Q30	Process 11 Distribution Of Mail Distributing incoming post to correct person Current Known Risk Royal Mail fail to deliver post 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 if required 	Further Action Required on Issue
75407Q31	Process 14 Fax Paper Ensuring that fax reports have been generated for both sent and received faxes and ensuring there is paper in the fax machine Current Known Risk Phone lines go down The paper tray is empty 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 if required 	Further Action Required on Issue
75407Q32	Process 15 Filing and Archiving Paperwork to be filed in the correct order Current Known Risk Paperwork is filed incorrectly 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 if required 	Further Action Required on Issue
75407Q33	Process 21 Office Sales Projects Ensuring office job list is being updated and completed Current Known Risk Office is short staffed or over worked 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 if required 	Further Action Required on Issue

75407Q34	Process 22 Company Polycys Ensure the company polycys are still current and upto date Current Known Risk Company shoots of in directions that are not laid out in its polycys or does not meet its objectives 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 if required 	Further Action Required on Issue
75407Q35	Process 23 Company Objectives Ensure the company Objects are still current and upto date Current Known Risk Company shots of in directions that are not laid out in its objectives 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 if required 	Further Action Required on Issue
75407Q36	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 if required 	Further Action Required on Issue
75407Q37	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 if required 	Further Action Required on Issue
75407Q38	Process 36 Emailing Of Invoices Invoices are emailed to customers Current Known Risk Computer or network failure 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 if required 	Further Action Required on Issue
75407Q39	Process 57 Temporary Stock Notices To Review Memos on Stock references tagged as Temporary Current Known Risk That an out of date memo is left on the account 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 if required 	Further Action Required on Issue
75407Q40	Process 5859 Review Un-shipped Parcels audit and snap shot - this is an audit of a part of goods out, listing of the parcels that are sat waiting on a customer response Current Known Risk Customer forgets to come back to us and parcels stay ready for shipping. As the package is already pick pack and ready to leave the building all computer traces will show as shipped. 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 if required 	Further Action Required on Issue
75407Q41	Process 5871 Check Sale Or Returns Review the Sale or Return list in intrastats. Ensure it is up to date. Current Known Risk That goods could be sent to a customer or goods returned but the list is not updated 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 if required 	Further Action Required on Issue
75407Q42	Process 5872 Check Sale Or Returns Export Review the Sale or Return list in intrastats. Ensure it is up to date. Current Known Risk That goods could be sent to a customer or goods returned but the list is not updated 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 if required 	Further Action Required on Issue
75407Q43	Process 5875 Check Paypal For Orders Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox Current Known Risk Computer/network breakdown 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 if required 	Further Action Required on Issue
75407Q44	Process 5876 E.Commerce Cardea And Multiquote To Collect E.Commerce Cardea And Multiquote Orders Current Known Risk Orders go unnoticed 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 if required 	Further Action Required on Issue

75407Q45	Process 5877 Review Company Data To review the numbers of various departments. Showing increasing / reducing staff requirements Check Audit Roles Titles and Processes in Employee Roles and Titles. Check the Page for Red Crosses and potentially missing objectives Current Known Risk incorrect staff levels 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 if required 	Further Action Required on Issue
75407Q46	Process 5882 Send Post To Humanmed Humanmed post is received, it needs to be forwarded to Humanmed UK Sales Manager Current Known Risk Post is not sent 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 if required 	Further Action Required on Issue
75407Q47	Process 5887 Review ISO/EN Documents To Keep Products and Services up-to date with current regulations and standards Current Known Risk Shipping products and or services with below regulations and or standards 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 if required 	Further Action Required on Issue
75407Q48	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 if required 	Further Action Required on Issue
75407Q49	Process 5892 Checking EBay And Amazon For Orders And Messages Checking the eBay and Amazon accounts for orders that have not been emailed to the main inbox and checking to see if there are messages or questions. Current Known Risk Computer/network breakdown 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 if required 	Further Action Required on Issue
75407Q50	Process 5893 Answering Website Questions Answering any questions that are asked via the website from within Intrastat 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 if required 	Further Action Required on Issue
75407Q51	Process 5894 Checking Of Active List Check the Active Back orders ensure no orders get missed Current Known Risk List is not reviewed and orders do not get shipped 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 if required 	Further Action Required on Issue
75407Q52	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 if required 	Further Action Required on Issue
75407Q53	Process 5899 Proforma And Quote Chasing Chase outstanding Quotes and Proformas Current Known Risk Computer/network breakdown Not chased up. 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 if required 	Further Action Required on Issue
75407Q54	Process 5901 Link Call Log Contacts To The CRM To link new calls to Contacts in the CRM Current Known Risk Computer/network breakdown 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 if required 	Further Action Required on Issue
75407Q55	Process 5913 Check For Humanmed Orders In Logistics Mailbox Checking the logistics mailbox from within and the main inbox for outstanding Humanmed orders. Current Known Risk Computer/network breakdown 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 if required 	Further Action Required on Issue

75407Q56	Process 5943 Check Cardea And Multiquote Checking the Cardea and Multiquote websites for outstanding orders or requests Current Known Risk Computer/network breakdown 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 if required 	Further Action Required on Issue
75407Q57	Process 5949 Filling Credit Card Slips Inputting the accurate data on to our pre-printed credit card slips for processing on dispatch of good. Secure storing and processing Current Known Risk incorrect information slips left unsecured 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 if required 	Further Action Required on Issue
75407Q58	Process 6861 Management Meeting Review Weekly Meeting Non Minuted Management discussions on issues Current Known Risk the meeting wont be held 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 if required 	Further Action Required on Issue
75407Q59	Process 6866 Internal Process Verification Complete Systems Review Review the Internal Process and Verification's are suitable for the current standards PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20 Current Known Risk Review not 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 if required 	Further Action Required on Issue
75407Q60	Process 6898 GHX Web Pricing To review the GHX Web Pricing Current Known Risk That the prices are in correct and we may have to let them have the old price if we have not up dated them 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 if required 	Further Action Required on Issue
75407Q61	Process 6954 Back Orders Review - By Customer To check the back orders in the tray in goods out and check the active list back orders has been reviewed Current Known Risk goods not shipped in a timely manner 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 if required 	Further Action Required on Issue
75407Q62	Process 7070 Management Review To discuss any problems, to assess work load and staffing. To review issues. Current Known Risk Meetings not carried out regularly. 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 if required 	Further Action Required on Issue
75407Q63	Process 7120 General Maintenance Requirements Review any General Maintenance required on the physical Site(s) Current Known Risk no risks 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 if required 	Further Action Required on Issue
75407Q64	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 Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required 	Further Action Required on Issue
75407Q65	Process 7674 Check Repairs Ready For Invoice List Review the repairs ready For invoice List in intrastats. Current Known Risk That repairs will be missed. 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 if required 	Further Action Required on Issue
75407Q66	Process 7676 PDFing Of Invoices Viamed Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers NO LONGER REQUIRED AS DONE BY THE SYSTEM AUTOMATICALLY Current Known Risk Incorrect name given to Invoice when saving the PDF. customer gets incorrect invoice. 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 if required 	Further Action Required on Issue

75407Q67	Process 7678 Check Catalog 360 Circle For Quotes And Orders Checking the Catalog 360 Circle website for outstanding orders or requests SYSTEM NO LONGER USED Current Known Risk Computer/network breakdown 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 if required	Further Action Required on Issue
75407Q68	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 if required	Further Action Required on Issue
75407Q69	Process 7684 Repairs Ready For Quote Process Repairs Ready For Quote Current Known Risk If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods 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 if required	Further Action Required on Issue
75407Q70	Process 7685 Repairs Ready For Invoice Process Invoice for completed repairs. Current Known Risk repair has errors on it 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 if required	Further Action Required on Issue
75407Q71	Process 7686 Thorough Checking Of Awaiting Action Tray Check that outstanding orders with unresolved issues are being followed up and addressed Current Known Risk Computer/network breakdown 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 if required	Further Action Required on Issue
75407Q72	Process 7690 Ship Repairs Review the Repairs completed shelf and ship those items that are ready for return to the customer. Current Known Risk That a repair will be missed 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 if required	Further Action Required on Issue
75407Q73	Process 7693 Collect Repair Filing From Warehouse Collect the filing form the warehouse Current Known Risk paperwork has been 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 if required	Further Action Required on Issue
75407Q74	Process 7697 Yearly Pricing Review To review the current pricing and impact of increases Current Known Risk Getting this wrong can interfere with sales. 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 if required	Further Action Required on Issue
75407Q75	Process 7699 Shred Sensitive Paperwork In JL Office Shredding of sensitive information Current Known Risk Broken shredder 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 if required	Further Action Required on Issue
75407Q76	Process 7705 Checking For Uploaded Files Checking if a customer has uploaded an order directly to our website Current Known Risk Computer/network breakdown 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 if required	Further Action Required on Issue
75407Q77	Process 7709 Delivered not Invoiced Ensure invoices are generated for shipped orders Current Known Risk Computer/network breakdown delivery is missed and remains un invoiced. 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 if required	Further Action Required on Issue

75407Q78	Process 7712 Review Inward Payments Review the payments received to ensure proformas can be shipped Current Known Risk Computer network breakdown 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 if required 	Further Action Required on Issue
75407Q79	Process 7713 Review Roles And Responsibility 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 if required 	Further Action Required on Issue
75407Q80	Process 7735 Ensure SOR's Are Followed Up Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and the item(s) is returned as appropriate Current Known Risk Computer/network breakdown 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 if required 	Further Action Required on Issue
75407Q81	Process 7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products In order to sell in the USA / Canada Markets products need to be registered with the FDA. Current Known Risk Its harder to initially get on teh register than maintaining it. Inability to sell products in North America 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 if required 	Further Action Required on Issue
75407Q82	Process 7748 Check Repair Orders Check the orders against the customer paperwork, that we have generated, for the repair we have received in. Current Known Risk That details will be incorrect and it will affect the customer. That mistakes may be missed. 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 if required 	Further Action Required on Issue
75407Q83	Process 7749 Check Repair Quotes Check the quotes that we send out for the repairs we have received in. Current Known Risk That mistakes may be missed. That details will be incorrect and it will affect the customer. 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 if required 	Further Action Required on Issue
75407Q84	Process 7752 SRS Folder Ensure all outstanding repairs are being dealt with Current Known Risk repairs get stuck in the system 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 if required 	Further Action Required on Issue
75407Q85	Process 7758 Check For GHX Orders Check the emails for orders from GHX Current Known Risk Computer/network breakdown 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 if required 	Further Action Required on Issue
75407Q86	Process 7760 Send Service Offers Send letters to existing customers to remind them that a service is due on their equipment 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 if required 	Further Action Required on Issue
75407Q87	Process 7761 Send VST Delivery Notifications Emailing Notifications of shipments Current Known Risk Limited risks, and if the email fails to get delivered the customer will still receive their shipment. 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 if required 	Further Action Required on Issue
75407Q88	Process 7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats. Current Known Risk not clear regularly, accidental usage of an old ORDER number	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required:	Notes On Risk / Benefits statement if required 	Further Action Required on Issue

generated by mistake
Current Likly 2 Current Frequency 1

No Action Required

75407Q89	Process 7783 PDF VST Invoices And Purchase Orders Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers NOW DONE AUTOMATICALLY Current Known Risk Incorrect name given to Invoice when saving the PDF. customer gets incorrect invoice. 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 if required	Further Action Required on Issue
75407Q90	Process 7788 Petty Cash Reconciliation This is done annually, a report for the accountant. It shows the currency and amount that we have in the building at the last day of the year. Current Known Risk That the report is not done and therefore an accurate figure for the petty cash is not inputted into the 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 if required	Further Action Required on Issue
75407Q91	Process 7795 Answering UK Web Questions Answering any questions that are asked via the website from within Intrastats 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 if required	Further Action Required on Issue
75407Q92	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 if required	Further Action Required on Issue
75407Q93	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 Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q94	Process 7828 Review The Quality Policy Viamed To review the Quality policy and check it is still valid and upto date. Current Known Risk That the policy will go out of date 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 if required	Further Action Required on Issue
75407Q95	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 No risk 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 if required	Further Action Required on Issue
75407Q96	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 Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q97	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 if required	Further Action Required on Issue
75407Q98	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 if required	Further Action Required on Issue
75407Q99	Process 7838 Review VIAMED Feedback - Customer Feedback Negative Review Customer Feedback Negative	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Current Known Risk Rolling Issues No risk to process Current Likly 3 Current Frequency 1		Update 3.Serious Action Required: No Action Required		
75407Q100 Process 7839 Review VIAMED Feedback - Customer Complaints To Review Viamed Customer Complaints Current Known Risk Rolling Issue No Risk 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 if required	Further Action Required on Issue
75407Q101 Process 7842 Review VIAMED Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised Current Known Risk Rolling Issue, No Risk 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 if required	Further Action Required on Issue
75407Q102 Process 7845 7.1.4 Environment Of Operations Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. Merged into 7729 can close the tasks Current Known Risk no risk. to the process, however risk maybe some problems may be brought up that are better left un-brought up, which may result in loss of staff while dealing with a problem that is suddenly brought to light that was better not addressed. 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 if required	Further Action Required on Issue
75407Q103 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 if required	Further Action Required on Issue
75407Q104 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 if required	Further Action Required on Issue
75407Q105 Process 7857 Software Validation Stock Tracking Check To confirm Software Validation Stock Tracking Check, is functioning as expected Current Known Risk Stock gets mislaid in the warehouse 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 if required	Further Action Required on Issue
75407Q106 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 if required	Further Action Required on Issue
75407Q107 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 if required	Further Action Required on Issue
75407Q108 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 Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75407Q109 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 if required	Further Action Required on Issue

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

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