## Document VM3COP27.54 How to export import products into Shopify **Revision ID124814**

Suggested Upload Document Name: Risk Assesment For Updating Document ID124814 Completed by <u>Catrin Hird</u> 31 Jul 2023

	Risk Assesment P to include reviewing superseded stock information.				
Document V Risk	M3COP27.54 How to export import products into Shopify Revision ID124814	Is linked Does	to the Following S	_	F41
Assesment ID124814	Question	Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Furth Issue
124814Q0	Does this Update warrant updating Any External Parties due to any <b>Terms and Conditional Agreements</b> E.G. Notified Body or is the update a Significate change to any ISO Certifications		Risk Frequicy due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth Issue
124814Q1	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.		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q2	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.	Affect?	Risk Frequency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q3	Viamed Ltd ISO13485:2016 Section: 4.2 Documentation requirements		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q4	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		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth

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31/07/2023, 09:50 effective planning, operation, and control of its processes;

e) other documentation specified by applicable regulatory requirements.

## Viamed Ltd ISO13485:2016 Section: 4.2.4 12481405

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

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 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

1.Negligible Action Required: No Action Required

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## 124814Q6 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.

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## VST Ltd ISO9001:2015 Section: 4.3 124814Q7

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 sability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

1.Negligible Action Required: No Action Required

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124814Q8	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.	Affect?	Risk Freqency due to Update 1.Improbable  Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q9	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.		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q10	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.		Risk Freqency due to Update 1.Improbable  Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q11	VST Ltd ISO9001:2015 Section: 7.5.1 General 7.5.1 General The organization squality 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.		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	Furth
124814Q12	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.		Risk Frequency due to Update 1.lmprobable  Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q13	VST Ltd ISO9001:2015 Section: 7.5.3 Control of documented information		Risk Freqency 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	Furth
124814Q14	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.		Risk Frequicy due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q15	VST Ltd ISO9001:2015 Section: 8.2.4  Changes to requirements for products and services	Does Update	Risk Frequency due to Update  1.Improbable	Notes On Risk / Benefits statement if required	Furth Issue

			1.Negligible Action Required: No Action Required		
124814Q24	QProcess5934 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?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q25	QProcess7941 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.	Affect?	Risk Freqency due to Update 3.Occasional  Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth Issue
124814Q26	<sup>Q</sup> Process7987 Sync External Telephone Logs To Export Telephone logs from the phone system to intrastats		Risk Freqency due to Update 1.Improbable > Risk Likly Due to Update 1.Negligible > Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth Issue
124814Q27	QProcess7992 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?	Risk Freqency 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	Furth Issue
124814Q28	QProcess8001 Verification Stock Linked To Documents Verifiy stock is being linked to documents when required		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q29	©Process8027 Update Pricing For Viamed Shopify To make sure the pricing on the Shopify web shop is updated when the prices are updated in the companies. Regular checks to ensure all prices are correct.		Risk Freqency 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	Furth
124814Q30	©Process8029 Send Intercompany Invoices To Jean Send Inter Company Invoices to Jean. Download from sales page and email.		Risk Freqency 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	Furth
124814Q31	OProcessProcess 9 Distribution Of Faxes Distribute recieved faxs Current Known Risk lost faxes Current Likly 1 Current Frequency 1		Risk Frequency due to Update  1.Improbable  Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Furth Issue

124814Q32   "Aprocess/Process 11   Distribution Of Pear   Distribu				1.Negligible V Action Required: No Action Required		
Fax Paper Fax Paper Fax Raper Fax Raper Fax Raper Fax Raper Fax Raper Live and caparing there is paper in the fax machine Current Known Risk Paper Current Likly 1 Current Frequency 1  124814Q34  Suppose the paper and the fax machine Current Known Risk Company Shelves Current Known Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelve Current Known Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelves Current Known Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelves Current Known Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelves Current Known Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelves Current Known Risk Company Shelves Current Likly 1 Current Frequency 1  124814Q35  Suppose Process 22 Current Rown Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelves Current Likly 1 Current Frequency 1  124814Q36  Suppose Process 23 Current Likly 1 Current Frequency 1  124814Q37  Suppose Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelves Current Rown Risk Company Shelves of in directions that are not laid out in its policy or does and merit a Shelves Current Likly 1 Current Frequency 1  124814Q38  Suppose Risk Company Shelves of in directions that are not laid out in its policy or does and merit in Shelves Current Rown Risk Company Shelves Current Rown Risk Company Shelves of in directions that are not laid out in its policy or does and merit in Shelves Current Rown Risk Company Shelves of in directions that are not laid out in its policy or does and merit in Shelves Current Rown Risk Company Shelves of indirections that are not laid out in its policy or does and merit in Shelves Current Rown Risk Company Shelves (Risk Risk Risk Risk Risk Risk Risk Risk	124814Q32	Distribution Of Post Distributing incoming post to correct person Current Known Risk Royal Mail fail to deliver post	Update Affect?	due to Update  1.Improbable  Risk Likly Due to Update  3.Serious  Action Required: No Action	required	
Filing and Archiving Papervork to be filed in the correct order Current Known Risk Paperwork is filed incorrectly Current Likly I Current Frequency I  124814Q35  **ProcessProcess 21 Office Sales Projects Ensuring office job list is being updated and completed Current Likly 2 Current Frequency I  124814Q36  **ProcessProcess 22 Current Known Risk Office is short staffed or over worked Current Known Risk Office is short staffed or over worked Current Likly 2 Current Frequency I  124814Q36  **ProcessProcess 22 Current Known Risk Company shoots of in directions that are not laid out in its policys or does not meet its objectives Current Likly 1 Current Frequency I  124814Q37  **ProcessProcess 23 Current Likly 1 Current Frequency I  124814Q37  **ProcessProcess 23 Current Likly 1 Current Frequency I  124814Q37  **ProcessProcess 23 Current Likly 1 Current Frequency I  124814Q37  **ProcessProcess 23 Current Likly 1 Current Frequency I  124814Q37  **ProcessProcess 23 Current Likly 1 Current Frequency I  124814Q37  **ProcessProcess 23 Current Likly 1 Current Frequency I  124814Q38  **ProcessProcess 24 Current Likly 1 Current Frequency I  124814Q39  **ProcessProcess 25 Current Likly 1 Current Frequency I  124814Q39  **ProcessProcess 27 Current Likly 1 Current Frequency I  124814Q39  **ProcessProcess 27 Current Likly 1 Current Frequency I  124814Q39  **ProcessProcess 27 Current Likly 1 Current Frequency I  124814Q39  **ProcessProcess 27 Current Likly 2 Current Frequency I  124814Q39  **ProcessProcess 27 Current Likly 3 Current Frequency I  124814Q39  **ProcessProcess 27 Current Likly 3 Current Frequency I  124814Q39  **ProcessProcess 27 Current Likly 3 Current Frequency I  124814Q39  **ProcessProcess 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  124814Q39  **ProcessProcess 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  124814Q39  **ProcessProcess 28 Supplier Revie	124814Q33	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	Update Affect?	due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action	required	
Update   Current Known Risk Office is short staffed or over worked   No Action   Current Likly 2 Current Frequency 1   No   Risk Likly Due to   Update   2 Mnor   Action Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   Required   No Action   No Action   Required   No Action   Required   No Action   No Action   No Action   Required   No Action   No	124814Q34	Filing and Archiving Paperwork to be filed in the correct order Current Known Risk Paperwork is filed incorrectly	Update Affect?	due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action	required	
Company Policys Ensure the company policys are still current and upto date Current Known Risk Company shoots of in directions that are not laid out in its policys or does not meet its objectives Current Likly 1 Current Frequency 1  124814Q37 O-ProcessProcess 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  124814Q38 O-ProcessProcess 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  124814Q39 O-ProcessProcess 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  Logical due to Update Affect?  Limprobable V Risk Likly Due to Update Action Required  Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required  Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V Notes On Risk / Benefits statement if required Limprobable V N	124814Q35	Office Sales Projects Ensuring office job list is being updated and completed Current Known Risk Office is short staffed or over worked	Update Affect?	due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action	required	
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  124814Q38  ProcessProcess 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  Current Likly 3 Current Frequency 1  Current Rown Reviews Current Frequency 1  Current Likly 3 Current Frequency 1  Current Likly 3 Current Frequency 1  Current Known Risk that the task is missed that follow ups are missed Current 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 Likly Due to Update Affect?  I.Improbable V  Risk Likly Due to Update Affect?  I.Improbable V  No V Risk Likly Due to Update Affect?  I.Improbable V  Notes On Risk / Benefits statement if required Issue  Required  Issue  Fourth Ske Likly Due to Update Affect?  I.Improbable V  No Likly Due to Update Affect?  I.Improbable V  No Likly Due to Update Affect?  Notes On Risk / Benefits statement if required Issue  Indicate the supplier Review of their internal grading.  Notes On Risk / Benefits statement if required  Issue  Indicate the supplier Review of their internal grading.  Notes On Risk / Benefits statement if required  I.Improbable V  No V Risk Likly Due to Update  Affect?  I.Improbable V  No V Risk Likly Due to Update  I.Improbable V  No V Risk Likly Due to Update  I.Improbable V  No V Risk Likly Due to Update  I.Improbable V  No V Risk Likly Due to Update  I.Improbable V  No V Risk Likly Due to Update  I.Improbable V  No V Risk Likly Due to Update	124814Q36	Company Policys Ensure the company policys are still current and upto date Current Known Risk Company shoots of in directions that are not laid out in its policys or does not meet its objectives	Update Affect?	due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action	required	
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  124814Q39  ProcessProcess 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  Management Reviews And Quality Audits Update  4 Affect? 1.Improbable   No Action Required  Notes On Risk / Benefits statement if required  Issue  124814Q39  No ProcessProcess 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  No Risk Likly Due to Update Update  Vision Required  Notes On Risk / Benefits statement if required  Issue Update Update  Vision Required  Notes On Risk / Benefits statement if required  Issue Update  Update  Vision Required	124814Q37	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	Update Affect?	due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action	required	
Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  Update due to Update required Affect?  I.Improbable  Risk Likly Due to Update	124814Q38	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	Update Affect?	due to Update  1.Improbable  Risk Likly Due to Update  3.Serious  Action Required: No Action	required	
LINEAR NOWE BISK NUMBER CERTIFICATES OF OUR OF ORDER OF TRAVESCO INC.	124814Q39	Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485,	Update Affect?	due to Update  1.Improbable  Risk Likly Due to	required	

Check the Page for Red Crosses and potentially missing objectives

Current Likly 3 Current Frequency 1

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124814Q56	QProcessProcess 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		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth Issue
124814Q57	Check For Humanmed Orders In Logistics Mailbox Checking the logistics mailbox from within and the main inbox for outstanding Humanmed orders.  NO LONGER REQUIRED HUMANEMD STOPPED Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1		Risk Frequicy due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q58	OprocessProcess 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		Risk Freqency due to Update 1.Improbable V Risk Likly Due to Update 2.Minor V Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q59	QProcessProcess 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		Risk Freqency due to Update 3.Occasional V Risk Likly Due to Update 1.Negligible V Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth Issue
124814Q60	OProcessProcess 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	Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q61	O ProcessProcess 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	Affect?	Risk Freqency due to Update  1.Improbable   Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q62	<sup>Q</sup> ProcessProcess 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	Affect?	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	Furth Issue
124814Q63	QProcessProcess 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		Risk Frequency due to Update 1.Improbable V Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Furth Issue

			1.Negligible V Action Required: No Action Required		
124814Q64	QProcessProcess 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?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q65	©ProcessProcess 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?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q66	OProcessProcess 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 comformances go unfixed Current Likly 2 Current Frequency 2		Risk Freqency due to Update  2.Remote   Risk Likly Due to Update  2.Minor   Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q67	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		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q68	QProcessProcess 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		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	Furtl Issue
124814Q69	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?	Risk Freqency due to Update 1.Improbable  Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q70	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?	Risk Freqency due to Update 1.Improbable  Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q71	QProcessProcess 7684 Repairs Ready For Quote Process Repairs Ready For Quote Current Known Risk If process does not get performed, we likly to loose customers.	Does Update Affect?	Risk Frequency due to Update  1.Improbable  Risk Likly Due to	Notes On Risk / Benefits statement if required	Furtl

Current Likly 2 Current Frequency 2

			2.Minor  Action Required: No Action Required		
124814Q80	QProcessProcess 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 🕶		Notes On Risk / Benefits statement if required	Furtl
124814Q81	QProcessProcess 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		Risk Frequicy due to Update  2.Remote  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl Issue
124814Q82	OprocessProcess 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		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  2.Minor  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q83	OProcessProcess 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	Affect?	Risk Frequicy due to Update  1.Improbable  Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q84	QProcessProcess 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 2		Risk Frequicy due to Update 2.Remote Visk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q85	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		Risk Freqency due to Update 2.Remote  Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furtl
124814Q86	CProcessProcess 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?		Notes On Risk / Benefits statement if required	Furtl
124814Q87	OProcessProcess 7758	Does	Risk Frequency	Notes On Risk / Benefits statement if	Furtl

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31/07/2023, 09	9:50 vmsecure.me.uk/intranet/databases/iso_documents/risk_a	asses_do	ocid.php?zz=1&A	=&vui=38&user=Catrin Hird&idp=raz	p4qI
	'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		Risk Likly Due to Update  1.Negligible  Action Required: No Action Required		
·	CyProcessProcess 8027 Update Pricing For Viamed Shopify To make sure the pricing on the Shopify web shop is updated when the prices are updated in the companies. Regular checks to ensure all prices are correct. Current Known Risk That a price will be missed and a customer buys the product at the previous price. Current Likly 1 Current Frequency 1		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
	<sup>Q</sup> ProcessProcess 8029 Send Intercompany Invoices To Jean Send Inter Company Invoices to Jean. Download from sales page and email. Current Known Risk that invoice will be missed Current Likly 1 Current Frequency 1		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
	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		Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement if required	Furth
124814Q115	Final Notes				

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 assessment button