Document VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd Revision ID31040

Suggested Upload Document Name: Risk Assesment For Updating Document ID31040 Completed by Derek Lamb 17 Nov 2021 **Reason for Risk Assesment** Minor Non Conformance from BSI Reporting time frame had not been updated Document VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd Revision ID31040 Is linked to the Following Standards and processes Risk Does Notes On Risk / Benefits statement if Further Action Required Assesment Question Update Risk on Update required on Issue ID31040 Affect Does this Update warrant updating Any External Parties due to any Terms and Does Risk Frequency Notes On Risk / Benefits statement if Further Action Required 31040Q0 Conditional Agreements E.G. Notified Body or is the update a Significate Update due to Update required on Issue change to any ISO Certifications Affect? 1.Improbable ➤ No **Y** Risk Likly Due to Update 1.Negligible Action Required: No Action Required Does Risk Fregency Further Action Required 3104001 Viamed Ltd ISO13485:2016 Section: 5.2 Notes On Risk / Benefits statement if Customer focus Update due to Update required on Issue Top management shall ensure that customer requirements and applicable Affect? 1.Improbable ➤ regulatory requirements are No V Risk Likly Due determined and met. to Update 1.Negligible Action Required: No Action Required Notes On Risk / Benefits statement if Further Action Required

Risk Frequency

31040Q2 Viamed Ltd ISO13485:2016 Section: 5.6.2 Review input

Affect? 1.Improbable > The input to management review shall include, but is not limited to, information arising from: No **→** Risk Likly Due a) feedback: to Update b) complaint handling; 1.Negligible ✓ c) reporting to regulatory authorities: Action d) audits: Required: e) monitoring and measurement of processes; No Action f) monitoring and measurement of product; Required g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; i) changes that could affect the quality management system; k) recommendations for improvement; 1) applicable new or revised regulatory requirements. 31040Q3 Viamed Ltd ISO13485:2016 Section: 7.2.3 Does Risk Fregency Notes On Risk / Benefits statement if Further Action Required Update due to Update Communication required on Issue Affect? 1.Improbable ➤ The organization shall plan and document arrangements for communicating No V Risk Likly Due with customers in relation to: to Update a) product information; 1.Negligible b) enquiries, contracts or order handling, including amendments; Action c) customer feedback, including complaints; Required: d) advisory notices. No Action The organization shall communicate with regulatory authorities in accordance Required with applicable regulatory requirements. Does Risk Fregency Notes On Risk / Benefits statement if Further Action Required 3104004 Viamed Ltd ISO13485:2016 Section: 8.2.2 Complaint handling Update due to Update required on Issue The organization shall document procedures for timely complaint handling in Affect? 1.Improbable > accordance with No Risk Likly Due applicable regulatory requirements. to Update These procedures shall include at a minimum requirements and responsibilities 1.Negligible Action a) receiving and recording information; Required: b) evaluating information to determine if the feedback constitutes a complaint; No Action c) investigating complaints; Required d) determining the need to report the information to the appropriate regulatory authorities: e) handling of complaint-related product; f) determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective

Update due to Update

required

on Issue

General

action resulting from the complaint handling process shall be documented. If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party

information shall be exchanged between the organization and the external party involved.

Complaint handling records shall be maintained (see 4.2.5).

31040O5 Viamed Ltd ISO13485:2016 Section: 8.2.3

Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting

criteria of adverse events or issuance of advisory notices, the organization shall document procedures

for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities shall be maintained (see 4.2.5).

Does Risk Frequency Update due to Update Affect? 1.Improbable Yes Risk Likly Due to Update 1.Negligible Action

Required: Needs Setting Notes On Risk / Benefits statement if required

Time scale for reporting updated

Time scale for reporting updated from 30 to 15Days,
Has no negative effect on the System

Further Action Required on Issue

31040O6 Via

Viamed Ltd ISO13485:2016 Section: 8.3.1

General

The organization shall ensure that product which does not conform to product requirements is

identified and controlled to prevent its unintended use or delivery. The organization shall document

a procedure to define the controls and related responsibilities and authorities for the identification,

documentation, segregation, evaluation, and disposition of nonconforming product.

The evaluation of nonconformity shall include a determination of the need for an investigation and

notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation,

any investigation and the rationale for decisions shall be maintained (see 4.2.5)

Does Risk Frequency Update due to Update Affect? 1.Improbable •

No V Risk Likly Due to Update

1.Negligible V

Action

Action Required: No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

31040Q7 Viamed Ltd ISO13485:2016 Section: 8.3.3

Actions in response to nonconforming product detected after delivery When nonconforming product is detected after delivery or use has started, the organization shall take

action appropriate to the effects, or potential effects, of the nonconformity.

Records of actions taken

shall be maintained (see 4.2.5).

The organization shall document procedures for issuing advisory notices in accordance with applicable

regulatory requirements. These procedures shall be capable of being put into

Does	Risk Frequency
Update	due to Update
Affect?	1.Improbable

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No 🗸	Risk Likly Due
	to Update
	1.Negligible ➤
	Action

Required: No Action Required

Notes On Risk / Benefits statement if required

Further Action Required
on Issue

4.2.5). 3104008 VST Ltd ISO9001:2015 Section: 5.1.2 Does Risk Fregency Notes On Risk / Benefits statement if Further Action Required Update due to Update required Customer focus on Issue Affect? 1.Improbable > 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to No • Risk Likly Due customer focus by to Update ensuring that: 1.Negligible ✓ a) customer and applicable statutory and regulatory requirements are Action determined, understood and Required: consistently met: No Action b) the risks and opportunities that can affect conformity of products and Required services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained. VST Ltd ISO9001:2015 Section: 10.2.2 Does Risk Fregency Notes On Risk / Benefits statement if Further Action Required 3104009 Update due to Update required on Issue The organization shall retain documented information as evidence of: Affect? 1.Improbable ➤ No Risk Likly Due a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action. to Update 1.Negligible ✓ Action Required: No Action Required 31040O10 \(\text{Process}7743 Risk Frequency Notes On Risk / Benefits statement if Further Action Required Does Update due to Update Customer Complaints Paper File required on Issue Affect? 1.Improbable ➤ Major Customer Complaints get escalated to Paper Customer Complaints file. No **→** Risk Likly Due Check the File is being Maintained and any relevant documentation is in the to Update File. 2.Minor V Action Required: No Action Required QProcess6931 Does Risk Frequency Further Action Required Notes On Risk / Benefits statement if 31040O11 Update due to Update **Customer Complaints** required on Issue Affect? 3.Occasional > Review the Customer Complaints Heading No Risk Likly Due

effect at any time. Records

of actions relating to the issuance of advisory notices shall be maintained (see

		to Update 1.Negligible Action Required: No Action Required	
31040Q12	CyProcess7839 Review VIAMED Feedback - Customer Complaints To Review Viamed Customer Complaints	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume to Update 1.Serious Action Required: No Action Required: No Action Required	enefits statement if Further Action Required on Issue
31040Q13	CyProcess7838 Review VIAMED Feedback - Customer Feedback Negative Review Customer Feedback Negative	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume to Update to Update 3.Serious Action Required: No Action Required: No Action Required	enefits statement if Further Action Required on Issue
31040Q14	Review VST Feedback - Customer Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume to Update 3.Serious Action Required: No Action Required Notes On Risk / Borrequired	enefits statement if Further Action Required on Issue
31040Q15	CyProcess7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised	Does Risk Frequency Update due to Update Affect? 1.Improbable Value Risk Likly Due	enefits statement if Further Action Required on Issue

		3. Ac Re No	Update Serious ction equired: o Action equired		
31040Q16	C Process 7842 Review VIAMED Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	Update du Affect? 1. No V Ris to 3. Acc Re No	sk Freqency te to Update Improbable sk Likly Due Update Serious ction equired: D Action equired	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q17	CProcess7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise	Update du Affect? 1. No V Ris to 3. Acc Re No	sk Frequency the to Update Improbable sk Likly Due Update Serious ction equired: Dequired	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q18	^Q Process7671 Humanmed Non Conformances Humanmed Non Conformances	Update du Affect? 2. No V Ris to 2. Acc Re No	e to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q19	QProcess7070 Management Review To discuss any problems, to assess work load and staffing. To review issues.	Update du Affect? 1.	sk Freqency the to Update Improbable • sk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

			to Update 2.Minor Action Required: No Action Required		
31040Q20	^Q Process7874 Review For Latest Version Med Dev 2.12. To Ensure we have the latest version of Med Dev 2.12. and update management if its been updated	Update Affect?	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q21	QProcessProcess 9 Distribution Of Faxes Distribute recieved faxs Current Known Risk lost faxes Current Likly 1 Current Frequency 1	Update Affect?	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q22	QProcessProcess 11 Distribution Of Mail Distibuting incoming post to correct person Current Known Risk Royal Mail fail to deliver post Current Likly 3 Current Frequency 1	Affect?	Risk Freqency 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
31040Q23	QProcessProcess 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		Risk Frequency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk Phone lines go down The paper tray is empty Current Likly 1 Current Frequency 1	to Update 1.Negligible Action Required: No Action Required
31040Q24	© ProcessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable Volume No Volume Risk Likly Due to Update 1.Negligible Volume Action Required: No Action Required: No Action Required Notes On Risk / Benefits statement if required on Issue Further Action Required on Issue
31040Q25	QProcessProcess 19 Maintaining Leaflet Stocks Ensure required leaflets are in stock Current Known Risk Stock is not checked Current Likly 2 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume to Update 2.Minor Action Required: No Action Required: No Action Required Notes On Risk / Benefits statement if required on Issue Further Action Required on Issue
31040Q26	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 Risk Frequency Update due to Update Affect? 1.Improbable Volume to Update 2.Minor Action Required: No Action Required: No Action Required Notes On Risk / Benefits statement if required on Issue Further Action Required on Issue
31040Q27	QProcessProcess 36 Emailing Of Invoices Invoices are emailed to customers	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume Risk Likly Due No Volume Risk Frequency Notes On Risk / Benefits statement if required on Issue

	Current Known Risk Computer or network failure Current Likly 2 Current Frequency 1		to Update 2.Minor Action Required: No Action Required		
31040Q28	Check the PO log is up to date with confirmations and expected shipping dates Current Known Risk The order is not checked and the supplier has not received it ergo we do not receive the order Current Likly 2 Current Frequency 1	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	Further Action Required on Issue
31040Q29	Customer Service Logs Ensuring customer onsite service visits are completed Current Known Risk Engineer or equipment is unavlailable 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	Further Action Required on Issue
31040Q30	CyprocessProcess 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	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	Further Action Required on Issue
31040Q31	QProcessProcess 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	Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	but the list is not updated Current Likly 2 Current Frequency 1		to Update 2.Minor Action Required: No Action Required		
31040Q32	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	Affect	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
31040Q33	QProcessProcess 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			Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q34	CProcessProcess 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	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	Further Action Required on Issue
31040Q35	© ProcessProcess 5882 Send Post To Humanmed Humanedmed post is received, it needs to be forwarded to Humanmed UK Sales Manager	Affect	Risk Frequency due to Update 1. Improbable Value Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk Post is not sent Current Likly 4 Current Frequency 1		to Update 4.Critical Action Required: No Action Required		
31040Q36	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	Affect?	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
31040Q37	QProcessProcess 5893 Answering Website 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	Update Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q38	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	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	Further Action Required on Issue
31040Q39	QProcessProcess 5895 Completing Office Job List Ensuring that the allocated tasks are being completed	Update Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk Office staff are too busy Current Likly 3 Current Frequency 1		to Update 3.Serious Action Required: No Action Required		
31040Q40	ProcessProcess 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	Update Affect?	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
31040Q41	ChrocessProcess 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	Update Affect?	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
31040Q42	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	Affect?	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
31040Q43	QProcessProcess 5943 Check Cardea And Multiquote Checking the Cardea and Multiquote websites for outstanding orders or requests	Update Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1		to Update 2.Minor Action Required: No Action Required		
31040Q44	CProcessProcess 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	Affect	Risk Frequency due to Update 3.0ccasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q45	QProcessProcess 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 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
31040Q46	Customer Complaints Review the Customer Complaints Heading Current Known Risk things are not followed up in a timely manner or are missed Current Likly 1 Current Frequency 3	Affect	Risk Frequency due to Update 3.0ccasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q47	© ProcessProcess 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	Affect	Risk Frequency due to Update [7] [1.Improbable] Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk goods not shipped in a timely manner Current Likly 1 Current Frequency 1		to Update 1.Negligible Action Required: No Action Required		
31040Q48	© ProcessProcess 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	Affect	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
31040Q49	Calibration Index To ensure that all equipment that requires calibration is done. In the correct timescale and manor. Current Known Risk That equipment we use to may not be calibrated when we need it. Current Likly 1 Current Frequency 2	Affect'	Risk Frequency due to Update 2 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
31040Q50	ApprocessProcess 7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems. Current Known Risk That there are duplicate orders o the system due to errors. Current Likly 3 Current Frequency 1	Affect	Risk Freqency 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
31040Q51	© ProcessProcess 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates.	Affect	Risk Frequency due to Update (2) [2.Remote] Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2	to Update 1.Negligible Action Required: No Action Required		
31040Q52	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 Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q53	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	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q54	Check Catalog 360 Circle For Quotes And Orders Checking the Catalog 360 Circle website for outstanding orders or requests Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q55	Check Stock For Proforma To check that we have stock in for customer proformas. Or review if any stock needs to be ordered.	Does Risk Frequency Update due to Update Affect? 1.lmprobable No Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1		to Update 2.Minor Action Required: No Action Required		
31040Q56	Chrocess 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	Update Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q57	© ProcessProcess 7685 Repairs Ready For Invoice Process Invoice for completed repairs. Current Known Risk repair has errors on it Current Likly 1 Current Frequency 1	Update Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q58	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	Affect?	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
31040Q59	OprocessProcess 7690 Ship Repairs Review the Repairs completed shelf and ship those items that are ready for return to the customer.	Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk That a repair will be missed Current Likly 2 Current Frequency 1	to Update 2.Minor Action Required: No Action Required	
31040Q60	ChrocessProcess 7691 Ship Sale Or Returns Review the sale or return shelf and ship those items. Current Known Risk Goods will be missed Current Likly 2 Current Frequency 1	s Risk Frequency late due to Update ect? 1.lmprobable Risk Likly Due to Update 2.Minor Action Required: No Action Required Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q61	Collect Repair Filing From Warehouse Collect the filing form the warehouse Current Known Risk paperwork has been missed Current Likly 1 Current Frequency 1	s Risk Frequency atte due to Update etct? 1.lmprobable V Risk Likly Due to Update 1.Negligible V Action Required: No Action Required	Further Action Required on Issue
31040Q62	QProcessProcess 7696 Send VIAMED Delivery Notifications Emailing Notifications of shipments Current Known Risk limited risks, and if email fails to get delivered the customer will still receive their shipment. Current Likly 2 Current Frequency 1	s Risk Frequency due to Update ect? 1.lmprobable V Risk Likly Due to Update 2.Minor Action Required: No Action Required Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q63	QProcessProcess 7697 Yearly Pricing Review To review the current pricing and impact of increases	s Risk Frequency late due to Update cct? 2.Remote Risk Likly Due Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk Getting this wrong can interfere with sales. Current Likly 1 Current Frequency 2	to Update 1.Negligible Action Required: No Action Required
31040Q64	© ProcessProcess 7699 Shred Sensitive Paperwork In JL Office Shredding of sensitive information Current Known Risk Broken shredder Current Likly 1 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume Now Risk Likly Due to Update 1.Negligible Volume Action Required: No Action Required Notes On Risk / Benefits statement if required on Issue Further Action Required on Issue Notes On Risk / Benefits statement if required on Issue Notes On Ri
31040Q65	CProcessProcess 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 Risk Frequency Update due to Update Affect? 2.Remote Volume Now Risk Likly Due to Update 2.Minor Action Required: No Action Required: No Action Required Notes On Risk / Benefits statement if required on Issue Further Action Required on Issue
31040Q66	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 Risk Frequency Update due to Update Affect? 1.Improbable Volume No Volume Risk Likly Due to Update 3.Serious Action Required: No Action Required Notes On Risk / Benefits statement if required on Issue Further Action Required on Issue
31040Q67	© ProcessProcess 7713 Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff,	Does Risk Frequency Update due to Update Affect? 2.Remote Value Risk Likly Due No Value Risk Frequency Risk Frequency Properties on Risk / Benefits statement if required on Issue Properties on Issue Properties of Risk Frequency Properties of Risk / Benefits statement if required on Issue Properties of Risk Frequency Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk / Benefits statement if required on Issue Properties of Risk Likly Due Properties Of Risk

	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		to Update 2.Minor Action Required: No Action Required		
31040Q68	ChrocessProcess 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	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	Further Action Required on Issue
31040Q69	QProcessProcess 7741 Review Ethical Policy Review the current Ethical Policy in intrastats Current Known Risk That something is missed that we would like to include Current Likly 1 Current Frequency 1	Update Affect?	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q70	Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file. Check the File is being Maintained and any relevant documentation is in the File. Current Known Risk Customer Complaints could be missed or not filed correctly Current Likly 2 Current Frequency 1	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	Further Action Required on Issue
31040Q71	A Process Process 7748 Check Repair Orders Check the orders against the customer paperwork, that we have generated, for the repair we have received in.	Update Affect?	Risk Freqency due to Update 1.Improbable V Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	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	to Update 2.Minor Action Required: No Action Required	
31040Q72	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 Risk Frequency Update due to Update Affect? 2.Remote Value to Update 2.Minor Action Required: No Action Required: No Action Required:	Required
31040Q73	CyProcessProcess 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 Risk Frequency Update due to Update Affect? 1.lmprobable Volume to Update 2.Minor Volume Action Required: No Action Required: No Action Required:	Required
31040Q74	QProcessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable Volume to Update 2.Minor Action Required: No Action Required: No Action Required:	Required
31040Q75	QProcessProcess 7760 Send Service Offers Send letters to existing customers to remind them that a service is due on their equipment	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume No Volume Risk Likly Due Notes On Risk / Benefits statement if required on Issue	Required

	Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1	to Update 1.Negligible Action Required: No Action Required		
31040Q76	CyprocessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q77	CyprocessProcess 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 generated by mistake Current Likly 2 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q78	QProcessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q79	Changing of the prices lists. Issue to check these are current	Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

31040Q80	*Vandagraph is not an ISO company Current Known Risk That people will quote the wrong price to the customer. Current Likly 1 Current Frequency 2 SprocessProcess 7792 Shipped Order Success Report A report is generated from figures in Intrastats to display how many orders have been shipped without errors Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1	Affect	to Update 1.Negligible Action Required: No Action Required Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action	Notes On Risk / Benefits statement if required	Further Action Required on Issue
			Required: No Action Required		2
31040Q81	© Process 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	Update Affect:	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31040Q82	Check Order Are Being Picked In Priority Order Check order are being picked in order of priority and date. Current Known Risk Orders going at before more urgent ones Current Likly 2 Current Frequency 1	Affect	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
31040Q83	© ProcessProcess 7798 Orders And Items Shipped Per Month Review the orders and items shipped per month	Affect's	Risk Frequency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk Problem with report Current Likly 3 Current Frequency 1		to Update 3.Serious Action Required: No Action Required		
31040Q84	QProcessProcess 7801 VST Price 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	Update 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	Further Action Required on Issue
31040Q85	OxProcessProcess 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	Update Affect?	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
31040Q86	CyprocessProcess 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	Affect?	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
31040Q87	QProcessProcess 7837 Review External Parties Influencing The QMS VST / Viamed To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks,	Update Affect?	Risk Frequency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Review the Underlining Processes and Tasks Current Known Risk External party has un-reviewed expectations Current Likly 1 Current Frequency 1	to Update 1.Negligible Action Required: No Action Required	•	
31040Q88	QProcessProcess 7838 Review VIAMED Feedback - Customer Feedback Negative Review Customer Feedback Negative Current Known Risk Rolling Issues No risk to process Current Likly 3 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 3.Serious Action Required: No Action Required	J	Further Action Required on Issue
31040Q89	CyrocessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 3.Serious Action Required: No Action Required		Further Action Required on Issue
31040Q90	QProcessProcess 7840 Review VST Feedback - Customer Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised Current Known Risk Rolling ISsue, No Risk Current Likly 3 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 3.Serious Action Required: No Action Required	J	Further Action Required on Issue
31040Q91	OProcessProcess 7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due		Further Action Required on Issue

	Current Known Risk Rolling ISsue, No Risk Current Likly 3 Current Frequency 1		to Update 3.Serious Action Required: No Action Required		
31040Q92	QProcessProcess 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	Update Affect?	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
31040Q93	CyrocessProcess 7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise Current Known Risk Rolling ISsue, No Risk Current Likly 3 Current Frequency 1	Update Affect?	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
31040Q94	QProcessProcess 7846 ISO System Management Review Viamed To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13 Current Known Risk Failure to do may cause major non conformites in QMS System Current Likly 1 Current Frequency 1	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	Further Action Required on Issue
31040Q95	QProcessProcess 7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards	Update Affect?	Risk Frequency due to Update 1.Improbable V Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	Current Known Risk No risks Rolling issue to perform task Current Likly 1 Current Frequency 1	to Update 1.Negligible Action Required: No Action Required
31040Q96	ChrocessProcess 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 Risk Frequency Update due to Update Affect? 3.Occasional Volume Now Risk Likly Due to Update 1.Negligible Volume Action Required: No Action Required: No Action Required
31040Q97	QProcessProcess 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 Risk Frequency Update due to Update Affect? 1.lmprobable Volume Now Risk Likly Due to Update 1.Negligible Volume Action Required: No Action Required: No Action Required: No Action Required
31040Q98	© Process Process 7872 Embargo Countries NOT Allowed To Sell To To review with the banks any embargo countries Current Known Risk Selling to an Embargo countries can get bank account frozen and loss of facilities Current Likly 1 Current Frequency 3	Does Risk Frequency Update due to Update Affect? 3.Occasional No Risk Likly Due to Update 1.Negligible Action Required: No Action Required Notes On Risk / Benefits statement if required on Issue Further Action Required on Issue
31040Q99	^Q ProcessProcess 7953 Vandagraph Delivery Notifications To Send Vandagraph Delivery notifications	Does Risk Frequency Update due to Update Affect? 1.Improbable Volume Risk Likly Due Notes On Risk / Benefits statement if required on Issue

Current Known Risk task not carried out Current Likly 1 Current Frequency 1		to Update 1.Negligible Action Required: No Action Required		
31040Q100 ProcessProcess 7957 Warehouse Requests Warehouse requests for stock to be reviewed, any shortages to be ordered or produced with a pro Current Known Risk Stock requirements fulfilled Current Likly 1 Current Frequency 1	Affec	Risk Freqency te due to Update t? 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
31040Q101 Document ID6098 QC 11 Customer Complaints In document	Upda Affec	Risk Freqency te due to Update t? 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
31040Q102 Document ID6096 QC 12 Customer Complaints R to this document	Upda Affec	Risk Freqency te due to Update t? 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
31040Q103 Does Generic CE File Attached to All Technical fi Of type 5 require any Notificaions and/or Risk ass	esment updates Upda Affec	Risk Frequency to due to Update to? 1.Improbable V	Notes On Risk / Benefits statement if required	Further Action Required on Issue

to Update			
1.Negligible	~		
Action			
Required:			
No Action			
Required			

31040Q104 Final Notes

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

SAVE FORM