

# Document VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd

## Revision ID75475

Suggested Upload Document Name: **Risk Assesment For Updating Document ID75475**

Completed by [Derek Lamb](#) 18 Oct 2023

### Reason for Risk Assesment

Added section on UKRP and Customer Complaints,  
removed reference to printing of SRN Barcodes

Document VOP 19 Feedback Customer Complaints Vigilance and Notifications Viamed Ltd Revision ID75475 Is linked to the Following Standards and processes

Risk Assesment ID75475	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75475Q0	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	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
75475Q1	Viamed Ltd ISO13485:2016 Section: 5.2 Customer focus Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.	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
75475Q2	Viamed Ltd ISO13485:2016 Section: 5.5 Responsibility, authority and communication	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

75475Q3	<p>Viamed Ltd ISO13485:2016 Section: 5.6.2 Review input</p> <p>General</p> <p>The input to management review shall include, but is not limited to, information arising from:</p> <ul style="list-style-type: none"> <li>a) feedback;</li> <li>b) complaint handling;</li> <li>c) reporting to regulatory authorities;</li> <li>d) audits;</li> <li>e) monitoring and measurement of processes;</li> <li>f) monitoring and measurement of product;</li> <li>g) corrective action;</li> <li>h) preventive action;</li> <li>i) follow-up actions from previous management reviews;</li> <li>j) changes that could affect the quality management system;</li> <li>k) recommendations for improvement;</li> <li>l) applicable new or revised regulatory requirements.</li> </ul>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likly Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
75475Q4	<p>Viamed Ltd ISO13485:2016 Section: 7.2.3</p> <p>Communication</p> <p>The organization shall plan and document arrangements for communicating with customers in relation to:</p> <ul style="list-style-type: none"> <li>a) product information;</li> <li>b) enquiries, contracts or order handling, including amendments;</li> <li>c) customer feedback, including complaints;</li> <li>d) advisory notices.</li> </ul> <p>The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likly Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
75475Q5	<p>Viamed Ltd ISO13485:2016 Section: 8.2.2</p> <p>Complaint handling</p> <p>The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements.</p> <p>These procedures shall include at a minimum requirements and responsibilities for:</p> <ul style="list-style-type: none"> <li>a) receiving and recording information;</li> <li>b) evaluating information to determine if the feedback constitutes a complaint;</li> <li>c) investigating complaints;</li> <li>d) determining the need to report the information to the appropriate regulatory authorities;</li> <li>e) handling of complaint-related product;</li> <li>f) determining the need to initiate corrections or corrective actions.</li> </ul> <p>If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented.</p> <p>If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likly Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

involved.

Complaint handling records shall be maintained (see 4.2.5).

75475Q6	<p>Viamed Ltd ISO13485:2016 Section: 8.2.3</p> <p>Reporting to regulatory authorities</p> <p>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).</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likly Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Added section on UKRP and Customer Complaints, removed reference to printing of SRN Barcodes</p>	<p>Further Action Required on Issue</p>
75475Q7	<p>Viamed Ltd ISO13485:2016 Section: 8.3.1</p> <p>General</p> <p>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)</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likly Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Added section on UKRP and Customer Complaints, removed reference to printing of SRN Barcodes</p>	<p>Further Action Required on Issue</p>
75475Q8	<p>Viamed Ltd ISO13485:2016 Section: 8.3.3</p> <p>Actions in response to nonconforming product detected after delivery</p> <p>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).</p> <p>The organization shall document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures shall be capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices shall be maintained (see 4.2.5).</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likly Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
75475Q9	<p>VST Ltd ISO9001:2015 Section: 5.1.2</p> <p>Customer focus</p> <p>5.1.2 Customer focus</p> <p>Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:</p> <p>a) customer and applicable statutory and regulatory requirements are determined,</p>	<p>Does Update Affect?</p> <p>No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likly Due to Update</p> <p>1.Negligible ▾</p> <p>Action Required:</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

understood and consistently met;  
b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;  
c) the focus on enhancing customer satisfaction is maintained.

No Action Required

75475Q10	VST Ltd ISO9001:2015 Section: 10.2.2	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
75475Q11	7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file.  Check the File is being Maintained and any relevant documentation is in the File.	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
75475Q12	6931 Customer Complaints Review the Customer Complaints Heading	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
75475Q13	7839 Review VIAMED Feedback - Customer Complaints To Review Viamed Customer Complaints	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
75475Q14	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

		Update 3.Serious Action Required: No Action Required		
75475Q15	7840 Review VST Feedback - Customer Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	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
75475Q16	7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised	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
75475Q17	7842 Review VIAMED Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	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
75475Q18	7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise	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
75475Q19	7671 Humanmed Non Conformances Humanmed Non Conformances	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update	Notes On Risk / Benefits statement if required Further Action Required on Issue

[https://www.vmsecure.me.uk/intranet/databases/iso\\_documents/risk\\_asses\\_docid.php?zz=1&A=&vui=2&user=Derek\\_Lamb&idp=rabPIHYj6uUW6&mph=&sessionid=81d81ffda838f29a287...](https://www.vmsecure.me.uk/intranet/databases/iso_documents/risk_asses_docid.php?zz=1&A=&vui=2&user=Derek_Lamb&idp=rabPIHYj6uUW6&mph=&sessionid=81d81ffda838f29a287...) 6/23

			3.Serious ▼ Action Required: No Action Required	
75475Q25	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
75475Q26	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
75475Q27	Process 19 Maintaining Leaflet Stocks Ensure required leaflets are in stock Current Known Risk Stock is not checked 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
75475Q28	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
75475Q29	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	Notes On Risk / Benefits statement if required Further Action Required on Issue

			2.Minor ▼ Action Required: No Action Required		
75475Q30	Process 5850 Purchase Order Log 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	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
75475Q31	Process 5857 Customer Service Logs Ensuring customer onsite service visits are completed Current Known Risk Engineer or equipment is unavailable 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
75475Q32	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
75475Q33	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
75475Q34	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	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

the list is not updated

Current Likly 2 Current Frequency 1

Update

2.Minor ▼

Action Required:

No Action Required

75475Q35	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
75475Q36	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
75475Q37	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
75475Q38	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
75475Q39	Process 5893 Answering Website Questions Answering any questions that are asked via the website from within Intrastats Current Known Risk Computer/network breakdown	Does Update Affect? No ▼	Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Current Likly 1 Current Frequency 1

1.Negligible ▼

Action Required:  
No Action Required

75475Q40	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
75475Q41	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
75475Q42	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
75475Q43	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
75475Q44	Process 5913 Check For Humanmed Orders In Logistics Mailbox Checking the logistics mailbox from within and the main inbox for outstanding Humanmed orders.	Does Update Affect? No ▼	Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Current Known Risk Computer/network breakdown  
Current Likly 2 Current Frequency 1

2.Minor ▼

Action Required:  
No Action Required

75475Q45	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 <div></div>	Further Action Required on Issue <div></div>
75475Q46	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 <div></div>	Further Action Required on Issue <div></div>
75475Q47	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 <div></div>	Further Action Required on Issue <div></div>
75475Q48	Process 6931 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	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 <div></div>	Further Action Required on Issue <div></div>
75475Q49	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	Does Update Affect? No ▼	Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due to Update	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

Current Known Risk goods not shipped in a timely manner  
Current Likly 1 Current Frequency 1

1.Negligible ▼

Action Required:  
No Action Required

75475Q50	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 <div></div>	Further Action Required on Issue <div></div>
75475Q51	Process 7091 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	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 <div></div>	Further Action Required on Issue <div></div>
75475Q52	Process 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	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 <div></div>	Further Action Required on Issue <div></div>
75475Q53	Process 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates. Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2	Does Update Affect? 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 <div></div>	Further Action Required on Issue <div></div>
75475Q54	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	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

			2.Minor ▼ Action Required: No Action Required	
75475Q55	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
75475Q56	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
75475Q57	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
75475Q58	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
75475Q59	Process 7685 Repairs Ready For Invoice Process Invoice for completed repairs. Current Known Risk repair has errors on it	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 Likly 1 Current Frequency 1		Update 1.Negligible Action Required: No Action Required			
75475Q60	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
75475Q61	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
75475Q62	Process 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	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
75475Q63	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
75475Q64	Process 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.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Current Likly 2 Current Frequency 1

2.Minor ▼

Action Required:  
No Action Required

75475Q65	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
75475Q66	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
75475Q67	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
75475Q68	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
75475Q69	Process 7713 Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff,  Current Known Risk That not all jobs will be allocated to a member of staff.	Does Update Affect? No ▼	Risk Frequency due to Update 2.Remote ▼ Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

That we may not share out jobs in a appropriate way.

Risk of being over faced.

Current Likly 2 Current Frequency 2

2.Minor ▼

Action Required:

No Action Required

75475Q70	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
75475Q71	Process 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	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
75475Q72	Process 7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file.  Check the File is being Maintained and any relevant documentation is in the File. Current Known Risk Customer Complaints could be missed or not filed correctly Current Likly 2 Current Frequency 1	Does Update Affect? No ▼	Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due to Update 2.Minor ▼ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75475Q73	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
75475Q74	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.	Does Update Affect? No ▼	Risk Frequency due to Update 2.Remote ▼ Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

That details will be incorrect and it will affect the customer.  
Current Likly 2 Current Frequency 2

2.Minor ▼

Action Required:  
No Action Required

75475Q75	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 <div></div>	Further Action Required on Issue <div></div>
75475Q76	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 <div></div>	Further Action Required on Issue <div></div>
75475Q77	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 <div></div>	Further Action Required on Issue <div></div>
75475Q78	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 <div></div>	Further Action Required on Issue <div></div>
75475Q79	Process 7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats.	Does Update Affect? No ▼	Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due to Update	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

Current Known Risk not clear regularly, accidental usage of an old ORDER number generated by mistake  
Current Likly 2 Current Frequency 1

2.Minor ▼

Action Required:  
No Action Required

75475Q80 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

75475Q81 Process 7791  
Price List Check  
Changing of the prices lists.  
Issue to check these are current  
  
\*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

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

75475Q82 Process 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

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

75475Q83 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

75475Q84 Process 7797  
Check Order Are Being Picked In Priority Order

Does  
Update

Risk Frequency due  
to Update

Notes On Risk / Benefits statement if  
required

Further Action Required on  
Issue

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?  
No ▼

1.Improbable ▼

Risk Likly Due to Update

2.Minor ▼

Action Required:  
No Action Required

75475Q85 Process 7798  
Orders And Items Shipped Per Month  
Review the orders and items shipped per month  
Current Known Risk Problem with report  
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

75475Q86 Process 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

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

75475Q87 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

75475Q88 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

75475Q89 Process 7837  
Review External Parties Influencing The QMS VST / Viamed

Does Update

Risk Frequency due to Update

Notes On Risk / Benefits statement if required

Further Action Required on Issue

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

Affect?  
 No ▼

1.Improbable ▼

Risk Likly Due to Update

1.Negligible ▼

Action Required:  
 No Action Required

75475Q90	Process 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 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
75475Q91	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
75475Q92	Process 7840 Review VST Feedback - Customer Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised Current Known Risk 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
75475Q93	Process 7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance 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
75475Q94	Process 7842 Review VIAMED Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised	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 ISsue, No Risk  
Current Likly 3 Current Frequency 1

Update

3.Serious ▼

Action Required:  
No Action Required

75475Q95	Process 7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise Current Known Risk 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
75475Q96	Process 7846 ISO System Management Review Viamed To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13  Current Known Risk Failure to do may cause major non conformites in QMS System Current Likly 1 Current Frequency 1	Does Update Affect? No ▼	Risk Frequency due to Update 1.Improbable ▼ Risk Likly Due to Update 1.Negligible ▼ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
75475Q97	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
75475Q98	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
75475Q99	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	Notes On Risk / Benefits statement if required	Further Action Required on Issue

		1.Negligible ▾ Action Required: No Action Required	
75475Q100 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 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
75475Q101 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
75475Q102 Process 7957 Warehouse Requests Warehouse requests for stock to be reviewed, any shortages to be ordered or produced with a production Job Current Known Risk Stock requirements fulfilled 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
75475Q103 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
75475Q104 Final Notes No ISO Procedures or Process are negativly affected by updating this document with the new document proposed			

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