# Document VM3COP20.80 GDPR Flow of data through the companies Revision ID113208

Suggested Upload Document Name: **Risk Assesment For Updating Document ID113208**
Completed by Derek Lamb 14 Mar 2025
**Reason for Risk Assesment**

Document VM3COP20.80 GDPR Flow of data through the companies Revision ID113208 Is linked to the Following Standards and processes

| Risk Assesment ID113208 | Question | Does Update Affect | Risk on Update | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
|---|---|---|---|---|---|
| 113208Q0 | Does this Update warrant updating Any External Parties due to any **Terms and Conditional Agreements** E.G. Notified Body or is the update a Significate change to any ISO Certifications | Does Update Affect? No | Risk Freqency due to Update 1.Improbable<br>Risk Likly Due to Update 1.Negligible<br>Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 113208Q1 | Viamed Ltd ISO13485:2016 Section: 7.3.6<br>Design and development verification<br>Design and development verification shall be performed in accordance with planned and documented<br>arrangements to ensure that the design and development outputs have met the design and development<br>input requirements.<br>The organization shall document verification plans that include methods, acceptance criteria and, as<br>appropriate, statistical techniques with rationale for sample size.<br>If the intended use requires that the medical device be connected to, or have an interface with, other<br>medical device(s), verification shall include confirmation that the design outputs meet design inputs<br>when so connected or interfaced.<br>Records of the results and conclusions of the verification and necessary actions shall be maintained<br>(see 4.2.4 and 4.2.5). | Does Update Affect? No | Risk Freqency due to Update 1.Improbable<br>Risk Likly Due to Update 1.Negligible<br>Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 113208Q2 | Viamed Ltd ISO13485:2016 Section: 7.3.7<br>Design and development validation<br>Design and development validation shall be performed in accordance with planned and documented<br>arrangements to ensure that the resulting product is capable of meeting the requirements for the<br>specified application or intended use.<br>The organization shall document validation plans that include methods, acceptance criteria, and, as<br>appropriate, statistical techniques with rationale for sample size.<br>Design validation shall be conducted on representative product. Representative product includes<br>initial production units, batches or their equivalents. The rationale for the choice of product used for<br>validation shall be recorded (see 4.2.5).<br>As part of design and development validation, the organization shall perform clinical evaluations or<br>performance evaluations of the medical device in accordance with applicable regulatory requirements.<br>A medical device used for clinical evaluation or performance evaluation is not considered to be released<br>for use to the customer.<br>If the intended use requires that the medical device be connected to, or have an interface with, other<br>medical device(s), validation shall include confirmation that the requirements for the specified<br>application or intended use have been met when so connected or interfaced.<br>Validation shall be completed prior to release for use of the product to the customer.<br>Records of the results and conclusion of validation and necessary actions shall be maintained (see<br>4.2.4 and 4.2.5). | Does Update Affect? No | Risk Freqency due to Update 1.Improbable<br>Risk Likly Due to Update 1.Negligible<br>Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 113208Q3 | Viamed Ltd ISO13485:2016 Section: 7.5.6<br>Validation of processes for production and service provision<br>The organization shall validate any processes for production and service provision where the resulting<br>output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence,<br>deficiencies become apparent only after the product is in use or the service has been delivered.<br>Validation shall demonstrate the ability of these processes to achieve planned results consistently.<br>The organization shall document procedures for validation of processes including:<br>a) defined criteria for review and approval of the processes;<br>b) equipment qualification and qualification of personnel;<br>c) use of specific methods, procedures and acceptance criteria;<br>d) as appropriate, statistical techniques with rationale for sample sizes<br>e) requirements for records (see 4.2.5);<br>f) revalidation, including criteria for revalidation;<br>g) approval of changes to the processes.<br>The organization shall document procedures for the validation of the application of computer software<br>used in production and service provision. Such software applications shall be validated prior to initial<br>use and, as appropriate, after changes to such software or its application. The specific approach and<br>activities associated with software validation and revalidation shall be proportionate to the risk | Does Update Affect? No | Risk Freqency due to Update 1.Improbable<br>Risk Likly Due to Update 1.Negligible<br>Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |

associated with the use of the software including the effect on the ability of the product to conform to
specifications.
Records of the results and conclusion of validation and necessary actions from the validation shall be
maintained (see 4.2.4 and 4.2.5).

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113208Q4 Viamed Ltd ISO13485:2016 Section: 8.1
General
The organization shall plan and implement the monitoring, measurement, analysis and improvement
processes needed to:
a) demonstrate conformity of product;
b) ensure conformity of the quality management system;
c) maintain the effectiveness of the quality management system.
This shall include determination of appropriate methods, including statistical techniques, and the
extent of their use.

Does Update Affect? No
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

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113208Q5 Viamed Ltd ISO13485:2016 Section: 8.4
Analysis of data
The organization shall document procedures to determine, collect and analyse appropriate data
to demonstrate the suitability, adequacy and effectiveness of the quality management system. The
procedures shall include determination of appropriate methods, including statistical techniques and
the extent of their use.
The analysis of data shall include data generated as a result of monitoring and measurement and from
other relevant sources and include, at a minimum, input from:
a) feedback;
b) conformity to product requirements;
c) characteristics and trends of processes and product including opportunities for improvement;
d) suppliers;
e) audits;
f) service reports, as appropriate.
If the analysis of data shows that the quality management system is not suitable, adequate or effective,
the organization shall use this analysis as input for improvement as required in 8.5.
Records of the results of analyses shall be maintained (see 4.2.5).

Does Update Affect? Yes
Risk 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: Update to come into Compliance.
Further Action Required on Issue

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113208Q6 Process7930
Review Flow Of Data
Flow of GDPR Data through the companys

Does Update Affect? No
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

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113208Q7 ProcessProcess 7834
Financial Review
The review the Financial requirements
Current Known Risk Non
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q8 ProcessProcess 27
Management Reviews And Quality Audits
To review and close all automatic rolling Issues.
Including all rolling tasks and audits
Current Known Risk that the task is missed
that follow ups are missed
Current Likly 3 Current Frequency 1

Does Update Affect? No
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

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113208Q9 ProcessProcess 5877
Review Company Data
To review the numbers of various departments.
Showing increasing / reducing staff requirements
Check Audit Roles Titles and Processes in Employee Roles and Titles.
Check the Page for Red Crosses and potentially missing objectives
Current Known Risk incorrect staff levels
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk 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

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113208Q10 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

Does Update Affect? No
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

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113208Q11 ProcessProcess 7830
Review Q.A. Failures Report
To review the Quantities of Failed product per Stock reference Passing through the Q.A. system
Current Known Risk That a high proportion of a product might fail QA and not be flagged
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk 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

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113208Q12 ProcessProcess 7837
Review External Parties Influencing The QMS VST / Viamed
To Review the External Parties Influencing The QMS VST / Viamed
Checked the Scopes and Risks,
Review the Underlining Processes and Tasks

Does Update Affect? No
Risk Freqency 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 External party has un-reviewed expectations
Current Likly 1 Current Frequency 1

1.Negligible
Action Required:
No Action Required

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113208Q13 ProcessProcess 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 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

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113208Q14 ProcessProcess 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 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

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113208Q15 ProcessProcess 7840
Review VST Feedback - Customer Feedback Negative
To review Negative feedback form Products
see if Non Conformance or customer Complaints need to be raised
Current Known Risk That an issue or report might be missed.
That a Negative feedback form Products might not be reviewed
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk 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

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113208Q16 ProcessProcess 7841
Review VST Feedback - Customer Complaints
To review Customer Complaints
see if Non Conformance need to be raised
Current Known Risk things are not followed up in a timely manner or are missed
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk 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

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113208Q17 ProcessProcess 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 That an issue or report might be missed.
That a Negative feedback form Products might not be reviewed
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk 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

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113208Q18 ProcessProcess 7843
Review VST Product Feedback Negative
To review Negative feedback form Products
see if Non Conformance or customer Complaints need to be raise
Current Known Risk Issues could be missed
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk 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

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113208Q19 ProcessProcess 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 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

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113208Q20 ProcessProcess 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 Freqency due to Update 3.Occasional
Risk Likly Due to Update 1.Negligible
Action Required:
No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

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113208Q21 ProcessProcess 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 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

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113208Q22 ProcessProcess 7874
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
Current Known Risk Using out of date Med Dev
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q23 ProcessProcess 7876
Maintain Update Of ISO Route Maps
To review
Route map VIAMED 13485:2016

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to
Notes On Risk / Benefits statement if required
Further Action Required on Issue

and VST 9001:2015

See if a new Summary sheet needs producing,
print new PDF, and upload on top of the old summary

Current Known Risk Summary sheet gets out of date.
Current Likly 2 Current Frequency 1

Update
2.Minor
Action Required:
No Action Required

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113208Q24 ProcessProcess 7878
Review Possible Upcoming Regulation Changes
Review possible legal / regulator changes that might affect Viamed / VST
Current Known Risk Legal / Regulatory changes stop us being able to carry out our processes as per QMS
Current Likly 1 Current Frequency 3

Does Update Affect? No
Risk Freqency due to Update 3.Occasional
Risk Likly Due to Update 1.Negligible
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

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113208Q25 ProcessProcess 7870
Software Validation Non Conformance Product Risk Feedback Loop
Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report.
Current Known Risk issues not carried out
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q26 ProcessProcess 7879
Software Validation Scheduled Tasks And Audits
To check the Scheduled Tasks and Audits is working as Intended.
To also Check the Out of Date documents is working as Intended.
Current Known Risk Tasks and Audit Rolling Issues Key to ISO requirements.
risk of losing standards
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q27 ProcessProcess 7850
Software Validation Scan Incorrect Product
Test the Goods out process disabling picking of items not relating to an order
Current Known Risk system allows incorrect items to be picked to customer orders
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q28 ProcessProcess 7851
Software Validation Scan Un-QA Product To Order
To test intrastats does not allow picking of unprocessed products to live customer orders
Current Known Risk Unprocessed product gets out into the field, resulting in recalls
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q29 ProcessProcess 7852
Software Validation Expired Stock
To attempt to Scan a product that has gone past its expire date.
Current Known Risk Expired product leaves the building and unusable products get to customers
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q30 ProcessProcess 7853
Software Validation Non Sell Able Shelf
Warehouse shelfs can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders.

Test that Order picking cannot pick unsellable stock locations to an Order
Current Known Risk quarantine stock leaves the building to a customer order, or stock on hold for a customer gets shipped to another customer.
Current Likly 1 Current Frequency 3

Does Update Affect? No
Risk Freqency due to Update 3.Occasional
Risk Likly Due to Update 1.Negligible
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

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113208Q31 ProcessProcess 7854
Software Validation In Production List
Software Validation of the production lists.

By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated
Current Known Risk Software tracking of production jobs fails.
Current Likly 2 Current Frequency 2

Does Update Affect? No
Risk Freqency due to Update 2.Remote
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

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113208Q32 ProcessProcess 7855
Software Validation - Production Lists
Software Validation - Production Lists
Review the current active production lists inintrastats to the actual in progress production lists
Current Known Risk Software inaccuracys in production
Current Likly 2 Current Frequency 2

Does Update Affect? No
Risk Freqency due to Update 2.Remote
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

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113208Q33 ProcessProcess 7856
Software Validation Unchecked Orders
To check order picking cannot pick against an unchecked order
Current Known Risk Customer recieves incorrect items due to order not being checked.
Current Likly 2 Current Frequency 2

Does Update Affect? No
Risk Freqency due to Update 2.Remote
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

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113208Q34 ProcessProcess 7857
Software Validation Stock Tracking Check
To confirm Software Validation Stock Tracking Check, is functioning as expected
Current Known Risk Stock gets mislaid in the warehouse
Current Likly 2 Current Frequency 1

Does Update Affect? No
Risk 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

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113208Q35 ProcessProcess 7858
Software Validation Attempt To QA Some Stock
Test the QA System that Staff not trained for QA are unable to QA a Product.
Current Known Risk Untrained staff QA/Processing Product
Current Likly 1 Current Frequency 3

Does Update Affect? No
Risk Freqency due to Update 3.Occasional
Risk Likly Due to Update 1.Negligible
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

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113208Q36 ProcessProcess 7861
Software Validation Of Training Documents Forced Reading
Software Validating Of Training Documents via Forced Required Reading
Current Known Risk required reading not read.
Current Likly 1 Current Frequency 2

Does Update Affect? No
Risk Freqency 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

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113208Q37 ProcessProcess 7865
Software Validation Conflicting Audits
Software Validiation of the system:
To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit.

Current Known Risk non Automatic
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q38 ProcessProcess 7875
Software Validation Document Control
To test document control is working as intended.
Current Known Risk If not carried out, document index is unvalidated
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q39 ProcessProcess 7880
Software Validation Out Of Date Documents
To confirm the out of documents computer software functions as expected flagging out of date items on to the list
Current Known Risk Old document in the system
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q40 ProcessProcess 7881
Software Validation - Live Orders
To compare Opera Live Orders to Intrastats Back order Active List

NO LONGER REQUIRED
Opera is now out of the system
Current Known Risk no risks, confirmation back orders is working as inteneded
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q41 ProcessProcess 8026
Automotive Competitor Price Review
To review competitor automotive prices

Current Known Risk That we may miss a event that has caused a large increase or decease in competitor prices.
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q42 ProcessProcess 7172
CE Technical Files
Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.
Current Known Risk Non conforming product out on the market
Current Likly 1 Current Frequency 1

Does Update Affect? No
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

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113208Q43 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 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

113208Q44 Final Notes

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No ISO Procedures or Process
are negativly affected by updating this document with the new document proposed
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SAVE FORM Only saves your progress in filling in above Questions - No feed back to pressing save form button
Once Form Complete Print Page to PDF (Landscape mode prefereable), go back to document upload page and upload to risk assesment button