

Document VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection

Revision ID73779

Suggested Upload Document Name: **Risk Assesment For Updating Document ID73779**

Completed by Derek Lamb 17 Nov 2021

Reason for Risk Assesment

ADDED to SRS Section
SEE VM3COP27.51 Incoming / Goods in Contamination Control before handling returned goods.

Document VOP 20 Goods in Purchases, Returns, Repairs, Inspection / Rejection Revision ID73779 Is linked to the Following Standards and processes

Risk Assesment Question ID73779	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
73779Q0 Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
73779Q1 Viamed Ltd ISO13485:2016 Section: 5.4.1 Quality objectives Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	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
73779Q2 Viamed Ltd ISO13485:2016 Section: 6.4.2	Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required

Contamination control

As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

Update due to Update
Affect?
 Risk Likly Due to Update
Action
Required:
Needs Setting

required
SEE VM3COP27.51 Incoming / Goods in Contamination Control before handling returned goods.
Change does not affect ISO system or create any added risk

on Issue

73779Q3 Viamed Ltd ISO13485:2016 Section: 7.4.1

Purchasing process

The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.

The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

- a) based on the supplier's ability to provide product that meets the organizations requirements;
- b) based on the performance of the supplier;
- c) based on the effect of the purchased product on the quality of the medical device;
- d) proportionate to the risk associated with the medical device.

The organization shall plan the monitoring and re-evaluation of suppliers.

Supplier performance in

meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).

Does Risk Frequency
Update due to Update
Affect?
 Risk Likly Due to Update
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

73779Q4 Viamed Ltd ISO13485:2016 Section: 7.4.2

Purchasing information

Purchasing information shall describe or reference the product to be purchased, including as appropriate:

- a) product specifications;

Does Risk Frequency
Update due to Update
Affect?
 Risk Likly Due to Update

Notes On Risk / Benefits statement if required

Further Action Required on Issue

b) requirements for product acceptance, procedures, processes and equipment;
c) requirements for qualification of supplier personnel;
d) quality management system requirements.
The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.
Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.
To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).

1.Negligible ▾
Action
Required:
No Action
Required

73779Q5	<p>Viamed Ltd ISO13485:2016 Section: 7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.5).</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
73779Q6	<p>Viamed Ltd ISO13485:2016 Section: 7.5.1 Control of production and service provision Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required:</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

product characteristics;
d) availability and use of monitoring and measuring equipment;
e) implementation of defined operations for labelling and packaging;
f) implementation of product release, delivery and post-delivery activities.
The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

No Action
Required

73779Q7	<p>Viamed Ltd ISO13485:2016 Section: 7.5.8 Identification The organization shall document procedures for product identification and identify product by suitable means throughout product realization. The organization shall identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status shall be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed. If required by applicable regulatory requirements, the organization shall document a system to assign unique device identification to the medical device. The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
---------	--	---------------------------------	---	---	---

73779Q8	<p>Viamed Ltd ISO13485:2016 Section: 7.5.11 Preservation of product The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
---------	---	---------------------------------	---	---	---

cannot provide
preservation.
If special conditions are required, they shall be controlled and recorded (see
4.2.5).

73779Q9	<p>VST Ltd ISO9001:2015 Section: 8.5.2</p> <p>Identification and traceability</p> <p>The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.</p> <p>The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.</p> <p>The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely 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>
73779Q10	<p>VST Ltd ISO9001:2015 Section: 8.5.3</p> <p>Property belonging to customers or external providers</p> <p>The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.</p> <p>The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.</p> <p>When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.</p> <p>NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▾</p> <p>Risk Likely 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>
73779Q11	<p>7826</p> <p>Goods In Processes</p> <p>To Receive Goods from Suppliers</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update</p> <p>2.Remote ▾</p> <p>Risk Likely Due to Update</p> <p>2.Minor ▾</p> <p>Action Required:</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

No Action
Required

73779Q12 5898

Processing Depleted Sensors
Dispose of depleted oxygen sensors and send customer replacement disposal bags

Does
Update
Affect?

No ▾

Risk Frequency
due to Update

1.Improbable ▾

Risk Likely Due
to Update

1.Negligible ▾

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

73779Q13 7859

Check POR Files For Items Delivered But Not Removed From File
Checking of the POR Files For Items Delivered But Not Removed From File

Does
Update
Affect?

No ▾

Risk Frequency
due to Update

1.Improbable ▾

Risk Likely Due
to Update

3.Serious ▾

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

73779Q14 7976

Decontamination Of Incomming Products And Repairs
Decontamination Of Incomming Products And Repairs. Clean items and make
sure safe to handle. Use gloves where needed.

Does
Update
Affect?

Yes ▾

Risk Frequency
due to Update

2.Remote ▾

Risk Likely Due
to Update

2.Minor ▾

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if
required

VM3COP27.51 Incoming _ Goods in
Contamination Control added to the
system for clarity
does not negativly affect the ISO
system.

Further Action Required
on Issue

241917

73779Q15 Process 26

Company Resources
Overview of the Company using various data Reporting Screens
Current Known Risk Not enough resources to complete tasks
Current Likly 3 Current Frequency 1

Does
Update
Affect?

No ▾

Risk Frequency
due to Update

1.Improbable ▾

Risk Likely Due
to Update

3.Serious ▾

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

Action
Required:
No Action
Required

73779Q16 Process 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading. Current Known Risk Supplier certificates go out of date, or they lose ISO standards and we`re unaware Current Likly 1 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
73779Q17 Process 39 Enviromental Policy Document Review Ensure our Viamed Environment and WEEE Policycs are upto date and suitable for current legislation Current Known Risk Potential to break the Law of the land with unsuitable policycs 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>
73779Q18 Process 5855 Purchase Order Requirements Teledyne To contact Teledyne and confirm the purchase orders we have outstanding for them Current Known Risk That good that are required will not be available. 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>
73779Q19 Process 5858 Opera Stock Adjustments Opera Counts bulk stock in and issues stock out against orders. Multiple processes cause stock to be used internally, Opera requires a weekly update to bring the stock count into line with whats	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>

been used outside the invoicing systems

NO LONGER REQUIRED, New system live counts these now
Current Known Risk Stock valuations will get inaccurate if the process is not performed.

Current Likly 2 Current Frequency 1

2.Minor ▾
Action
Required:
No Action
Required

73779Q20 Process 5868

Return Goods To Suppliers
To get Returns numbers from suppliers with return shipments pending.
Current Known Risk Not performing the process can lead to products being returned within the warranty period causing financial loss.
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

73779Q21 Process 5877

Review Company Data
To review the numbers of various departments.
Showing increasing / reducing staff requirements
Current Known Risk incorrect staff levels
Current Likly 3 Current Frequency 1

Does
Update
Affect?
No ▾
Risk Frequency
due to Update
1.Improbable ▾
Risk Likly Due
to Update
3.Serious ▾
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

73779Q22 Process 5935

Stock Allocations
To allocate stock that has not automatically be linked to a repair or invoice.
Current Known Risk Items that should be linked to a invoice are not in the allocations list.
That items are allocated incorrectly on the list.
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

73779Q23 Process 6819

Supplier Payments and Invoice processing

Does
Update
Risk Frequency
due to Update

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

Inputting the invoices from suppliers for the correct month.
Ensuring they are all entered in to the correct period.
Current Known Risk invoices missed and therefore absent from accounts and
Vat return
Current Likly 1 Current Frequency 2

Affect? 2.Remote
No Risk Likly Due
to Update
1.Negligible
Action
Required:
No Action
Required

73779Q24 Process 6829
Supplier Review - Outstanding orders
Orders that have not been supplied in the time scale provided.
Current Known Risk That good will be delayed and therefore not available to
customers.
Current Likly 2 Current Frequency 2

Does Risk Frequency
Update due to Update
Affect? 2.Remote
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

73779Q25 Process 6832
Supplier Review Future orders
Orders that will be placed in the future.
Current Known Risk That we will not place the correct orders and the right
time.
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

73779Q26 Process 6838
Opera Negative Stock
To find and correct opera when it reads Negative stock values.

Current Known Risk Damage Opera.
Current Likly 1 Current Frequency 1

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

73779Q27 Process 6850

Does Risk Frequency Notes On Risk / Benefits statement if Further Action Required

Current Stock Levels
Review current stock levels
Current Known Risk If the levels are incorrect or we have a shortages then customers will not receive their goods in a timely manor.
Current Likly 2 Current Frequency 1

Update due to Update
Affect? 1.Improbable
No Risk Likly Due
to Update
2.Minor
Action
Required:
No Action
Required

required

on Issue

73779Q28 Process 6945

Missing Stock or Adjustments
To synchronise Opera stock Count against Intrastats internal movement of stock,
E.G. Items that wont uniquely appear on an opera order - such as production parts.

TASK IS NO LONGER REQUIRED
Current Known Risk Opera and Intrastats go out of sync
Current Likly 1 Current Frequency 1

Does Update
Affect? 1.Improbable
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

73779Q29 Process 6955

Production Requirements
To set production job for any stock item that is needed for customer back order, warehouse requests or marketing
Current Known Risk that jobs will not be added and customers orders will be delayed
Current Likly 2 Current Frequency 1

Does 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

73779Q30 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? 2.Remote
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

73779Q31 Process 7679	Check Stock Requirements Supplier Teledyne To check that we have stock in for customer proformas and orders. 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 <div></div>	Further Action Required on Issue <div></div>
73779Q32 Process 7680	Check Stock Requirements Supplier Envitec To check that we have stock in for customer proformas and orders. 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 <div></div>	Further Action Required on Issue <div></div>
73779Q33 Process 7681	Check Stock Requirements Supplier Posey To check that we have stock in for customer proformas and orders. 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 <div></div>	Further Action Required on Issue <div></div>
73779Q34 Process 7682	Check Stock Requirements Supplier Bluepoint To check that we have stock in for customer proformas and orders. 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 <div></div>	Further Action Required on Issue <div></div>

<p>73779Q35 Process 7683</p> <p>Check Stock For Proforma</p> <p>To check that we have stock in for customer proformas. Or review if any stock needs to be ordered.</p> <p>Current Known Risk That a customer is told we have stock and then we are unable to ship.</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q36 Process 7684</p> <p>Repairs Ready For Quote</p> <p>Process Repairs Ready For Quote</p> <p>Current Known Risk If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q37 Process 7685</p> <p>Repairs Ready For Invoice</p> <p>Process Invoice for completed repairs.</p> <p>Current Known Risk repair has errors on it</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q38 Process 7689</p> <p>Move Stock From QA Shelf To Stock Shelf Monday</p> <p>Move Stock From QA Shelf To Stock Shelf</p> <p>Current Known Risk That stock is not replaced so it will take longer to pick goods for orders.</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

<p>73779Q39 Process 7694</p> <p>Move Stock From QA Shelf To Stock Shelf Tuesday</p> <p>Move Stock From QA Shelf To Stock Shelf</p> <p>Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. The stock is not on the correct shelf.</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q40 Process 7695</p> <p>Top Up Quick Shipping Shelves</p> <p>Move Stock From QA Shelf To Quick Shipping Shelves</p> <p>Current Known Risk That stock is not replaced so it will take longer to pick goods for orders.</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q41 Process 7735</p> <p>Ensure SOR's Are Followed Up</p> <p>Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and the item(s) is returned as appropriate</p> <p>Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q42 Process 7737</p> <p>Production In Production List</p> <p>Review the Production List, check and list those items that were started more than 30 days ago have not been through QA.</p> <p>Audit is carried out and production is reviewed and chased at this point.</p> <p>Current Known Risk Production jobs is finished but not been QA, may get lost in the system</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="2.Remote"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

<p>73779Q43 Process 7784</p> <p>Check Returns Supplier Envitec Supplier returns to Envitec, return any products waiting to be returned Current Known Risk Product not returned so missing the supplier warranty Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q44 Process 7785</p> <p>Check Returns Supplier Teledyne Supplier returns to Teledyne, return any products waiting to be returned Current Known Risk Product not returned, risks not analysed Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q45 Process 7786</p> <p>Check Returns Supplier Maxtec Supplier returns to Maxtec, return any products waiting to be returned Current Known Risk Product not returned, risks not analysed Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>73779Q46 Process 7787</p> <p>Check Returns All Supplier Review the returns that are present in the duckets, for each supplier as per the issues. Current Known Risk Goods not returned in a timely manor so causing items to be out of warranty. Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="3.Serious"/></p> <p>Action Required:</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

No Action
Required

73779Q47	Process 7823 Saftey Tester Data Backup the Fluke ESA615 Safety tester CE Copy any files to the Z Drive - safety tester backupdata Current Known Risk That this will not be 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
73779Q48	Process 7826 Goods In Processes To Receive Goods from Suppliers Current Known Risk incorrectly booked in not booked in 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
73779Q49	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
73779Q50	Process 7882 Purchase Payments Pay suppliers within terms Current Known Risk pay the wrong amount or to the wrong company. Not pay in terms Current Likly 2 Current Frequency 2	Does Update Affect? No ▾	Risk Frequency due to Update 2.Remote ▾ Risk Likly Due to Update 2.Minor ▾	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Action
Required:
No Action
Required

73779Q51	Process 7923 Review Of Credits Received From Suppliers To Review and tidy up any outstanding RMAs that have been resolved by Supplier credit notes Current Known Risk credits missed or not received 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
73779Q52	Process 7933 Purchasing Invoice Processing Inputting the invoices from suppliers for the correct month. Ensuring they are all entered in to the correct period. Current Known Risk invoices missed and therefore absent from accounts and Vat return 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
73779Q53	Document ID9543 VM3COP05 Receipt of goods / Goods in in booking in stock Is Related to this document	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
73779Q54	Document ID23269 VM3COP06 Rejected Goods Is Related to this document	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

73779Q55 Document ID13703 VM3COP20.03 Repair Procedures Goods in Is Related to this document

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

73779Q56 Document ID24767 VM3COP29.09 Goods In - Booking In Returns processing repairs customer repair Is Related to this document

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

73779Q57 Document ID25364 VM3COP44.01 OxiQuant S QA Procedure Is Related to this document

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

73779Q58 Document ID9707 VM3COP51.15 Viamed Infant Resuscitation Cabinet Service Sheet Is Related to this document

Does
Update
Affect?

No ▼

Risk Frequency
due to Update

1.Improbable ▼

Risk Likly Due

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

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

73779Q59 Document ID22823 VM3COP51.50 Resuscitation Cabinet Service Toolbox
Check List Is Related to this document

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

73779Q60 Does Generic CE File Attached to All Technical file #2
Of type 5 require any Notificaions and/or Risk assesment updates

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

73779Q61 Final Notes

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

SAVE FORM