Process Update Details	Relevant Standard	Does update Affect	Risk Profile	Notes Issue
Process #27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits Updated On : 13 Nov 2021 Risks to the Process that the task is missed that follow ups are missed	Viamed Ltd ISO13485:2016 4.1.3 Quality management system For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this	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 that the task is missed that follow ups are missed Further Action Required on Issue 0	

International Standard and compliance with applicable regulatory requirements (see 4.2.5).

Process #27 Management Reviews And Quality Audits
To review and close all automatic rolling Issues. Including all rolling tasks and audits
Updated On : 13 Nov 2021
Risks to the Process
that the task is missed
that follow ups are missed

Viamed Ltd
ISO13485:2016
4.2.1 General Documentation requirements
The quality management system documentation (see 4.2.4) shall include:
a) documented statements of a quality policy and quality objectives;
b) a quality manual;
c) documented procedures and records required by this International Standard;
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;
e) other documentation specified by applicable regulatory requirements.

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
that the task is missed
that follow ups are missed
Further Action Required on Issue
0

Process #27 Management Reviews And Quality Audits
To review and close all

Viamed Ltd
ISO13485:2016
5.1 Management

Does Update Affect?
No
Risk Freqency

Notes On Risk / Benefits statement if required

automatic rolling Issues.
Including all rolling tasks and audits
Updated On : 13 Nov 2021
Risks to the Process
that the task is missed
that follow ups are missed

commitment
Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:
a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;
b) establishing the quality policy;
c) ensuring that quality objectives are established;
d) conducting management reviews;
e) ensuring the availability of resources.

due to Update
1.Improbable
Risk Likly Due to Update
3.Serious
Action Required:
No Action Required

that the task is missed
that follow ups are missed

Further Action Required on Issue
0

Process #27 Management Reviews And Quality Audits
To review and close all automatic rolling Issues.
Including all rolling tasks and audits
Updated On : 13 Nov 2021
Risks to the Process
that the task is missed
that follow ups are missed

Viamed Ltd
ISO13485:2016
5.6.1 General
The organization shall document procedures for management review. Top management shall review
the organization's quality management system at documented planned intervals to ensure its

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
that the task is missed
that follow ups are missed

Further Action Required on Issue
0

continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained

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Process #27 Management Reviews And Quality Audits

To review and close all automatic rolling Issues. Including all rolling tasks and audits

Updated On : 13 Nov 2021

Risks to the Process

that the task is missed

that follow ups are missed

Viamed Ltd

ISO13485:2016

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

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

that the task is missed
that follow ups are missed

Further Action Required on Issue

0

techniques, and the extent of their use.

Process #27 Management Reviews And Quality Audits
To review and close all automatic rolling Issues. Including all rolling tasks and audits
Updated On : 13 Nov 2021
Risks to the Process
that the task is missed
that follow ups are missed

Viamed Ltd ISO13485:2016
8.2.5 Monitoring and measurement of processes
The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall
be taken, as appropriate.

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
that the task is missed
that follow ups are missed

Further Action Required on Issue 0

Process #27 Management Reviews And Quality Audits
To review and close all automatic rolling Issues. Including all rolling tasks and audits
Updated On : 13 Nov 2021
Risks to the Process
that the task is missed
that follow ups are

VST Ltd ISO9001:2015
4.4.2 Quality management system and its processes
To the extent necessary, the organization shall:
a) maintain documented information to support the operation of its processes;
b) retain documented

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
that the task is missed
that follow ups are missed

Further Action Required on Issue 0

missed	information to have confidence that the processes are being carried out as planned.

Process #27 Management Reviews And Quality Audits

To review and close all automatic rolling Issues. Including all rolling tasks and audits

Updated On : 13 Nov 2021

Risks to the Process

that the task is missed

that follow ups are missed

VST Ltd ISO9001:2015 5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

c) ensuring the integration of the quality management system requirements into the organization's business processes;

d) promoting the use of the process approach and risk-based thinking;

e) ensuring that the resources needed for the

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

that the task is missed
that follow ups are missed

Further Action Required on Issue

0

quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private,

for profit or not for profit.

Process #27 Management Reviews And Quality Audits
To review and close all automatic rolling Issues. Including all rolling tasks and audits
Updated On : 13 Nov 2021
Risks to the Process
that the task is missed
that follow ups are missed

VST Ltd ISO9001:2015 9.1.3 Analysis and evaluation
The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.
The results of analysis shall be used to evaluate:
a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.
NOTE Methods to analyse data can include statistical techniques.

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
that the task is missed
that follow ups are missed

Further Action Required on Issue
0

Process #54 Gents Toilets

Bleech the Gents Toilets

Updated On : 02 Nov 2021

Input to the Process

cleaning products

Viamed Ltd

ISO13485:2016

6.3 Infrastructure

The organization shall document the requirements for the infrastructure needed to achieve
conformity to product requirements, prevent product mix-up and ensure orderly handling of product.
Infrastructure includes, as appropriate:
a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).
The organization shall document requirements for the maintenance activities, including the interval
of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in

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

job not carried out

Further Action Required on Issue

0

production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained

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Process #54 Gents Toilets
Bleech the Gents Toilets
Updated On : 02 Nov 2021
Input to the Process
cleaning products

Viamed Ltd
ISO13485:2016
6.4.1 Work environment
The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.
If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor
and control the work environment.
The organization shall:
a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the

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
job not carried out

Further Action Required on Issue
0

product or work environment could affect medical device safety or performance;
b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.
NOTE Further information can be found in ISO 14644 and ISO 14698

Process #57 Temporary Stock Notices
To Review Memos on Stock references tagged as Temporary
Updated On : 13 Nov 2021
Risks to the Process
That an out of date memo is left on the account

Viamed Ltd
ISO13485:2016
4.2.1 General Documentation requirements
The quality management system documentation (see 4.2.4) shall include:
a) documented statements of a quality policy and quality objectives;
b) a quality manual;
c) documented procedures and records required by this International Standard;
d) documents, including records, determined by the organization to be

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
That an out of date memo is left on the account

Further Action Required on Issue
0

necessary to ensure the effective planning, operation, and control of its processes;
e) other documentation specified by applicable regulatory requirements.

Process #5856 Cleaning
The Kitchen
to clean the kitchen, work tops and floor. make sure it is safe for people to use
Updated On : 13 Nov 2021
Scope
to clean the kitchen, work tops and floor. make sure it is safe for people to use

Viamed Ltd
ISO13485:2016
6.3 Infrastructure
The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product.
Infrastructure includes, as appropriate:
a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).
The organization shall document requirements for the maintenance activities, including the interval
of performing the

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
that it wont be cleaned and so not safe or nice to eat in

Further Action Required on Issue
0

maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained

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Process #5894 Checking Of Active List

Check the Active Back orders ensure no orders get missed

Updated On : 02 Nov 2021

Risks to the Process

List is not reviewed and orders do not get shipped

VST Ltd ISO9001:2015 4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;

b) the requirements of these interested parties

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

List is not reviewed and orders do not get shipped

Further Action Required on Issue

0

	that are relevant to the quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements.		

Process #5894 Checking Of Active List Check the Active Back orders ensure no orders get missed Updated On : 02 Nov 2021 Risks to the Process List is not reviewed and orders do not get shipped	VST Ltd ISO9001:2015 5.1.2 Customer focus 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, 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.	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 List is not reviewed and orders do not get shipped Further Action Required on Issue 0

Process #5894 Checking Of Active List Check the Active Back orders ensure no orders get missed Updated On : 02 Nov 2021 Risks to the Process List is not reviewed and orders do not get shipped	VST Ltd ISO9001:2015 6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. The organization shall maintain documented information on the quality objectives	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 List is not reviewed and orders do not get shipped Further Action Required on Issue 0

Process #5894 Checking Of Active List Check the Active Back orders ensure no orders get missed Updated On : 02 Nov 2021	VST Ltd ISO9001:2015 7.5.1 General 7.5.1 General The organization's quality management system shall include:	Does Update Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required

Risks to the Process
List is not reviewed and orders do not get shipped

a) documented information required by this International Standard;
b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.
NOTE The extent of documented information for a quality management system can differ from one organization to another due to:
- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

to Update
1.Negligible
Action Required:
No Action Required

List is not reviewed and orders do not get shipped

Further Action Required on Issue
0

Process #5894 Checking Of Active List
Check the Active Back orders ensure no orders get missed
Updated On : 02 Nov 2021
Risks to the Process
List is not reviewed and orders do not get shipped

VST Ltd ISO9001:2015 8.2.1 Customer communication
Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders,

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:

Notes On Risk / Benefits statement if required
List is not reviewed and orders do not get shipped

	including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	No Action Required	Further Action Required on Issue 0

Process #5894 Checking Of Active List Check the Active Back orders ensure no orders get missed Updated On : 02 Nov 2021 Risks to the Process List is not reviewed and orders do not get shipped	VST Ltd ISO9001:2015 8.2.3 Review of the requirements for products and services	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 List is not reviewed and orders do not get shipped Further Action Required on Issue 0

Process #5905 Price Checking Check we have consistent pricing across the different databases. Updated On : 02 Nov 2021 Outputs to the Process	VST Ltd ISO9001:2015 7.1.3 Infrastructure The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.	Does Update Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required:	Notes On Risk / Benefits statement if required Incorrect pricing can cause customer confusion Further Action Required on Issue 0

Valid and accurate pricing	NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology.	No Action Required

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Process #5919 Check Out Side Drain
Check outside drain is not BLocked
Updated On : 13 Nov 2021
Risks to the Process that we will have a flood

Viamed Ltd
ISO13485:2016
6.3 Infrastructure
The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product.
Infrastructure includes, as appropriate:
a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).
The organization shall document requirements

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
that we will have a flood

Further Action Required on Issue
0

for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained

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Process #5919 Check Out Side Drain
Check outside drain is not BLocked
Updated On : 13 Nov 2021
Risks to the Process that we will have a flood

Viamed Ltd
ISO13485:2016
6.4.1 Work environment
The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.
If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the

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
that we will have a flood

Further Action Required on Issue
0

work environment and the procedures to monitor and control the work environment.
The organization shall:
a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;
b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.
NOTE Further information can be found in ISO 14644 and ISO 14698

Process #5921 Clearing Water Downstairs Check the Archives for Signs of Water, ensure the pump is working Updated On : 13 Nov 2021 Risks to the Process	Viamed Ltd ISO13485:2016 6.3 Infrastructure The organization shall document the requirements for the infrastructure needed to achieve	Does Update Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement if required

that we will have a flood	conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained	2.Minor Action Required: No Action Required	that we will have a flood Further Action Required on Issue 0

Process #5921 Clearing Water Downstairs
Check the Archives for Signs of Water, ensure the pump is working
Updated On : 13 Nov 2021
Risks to the Process
that we will have a flood

Viamed Ltd
ISO13485:2016
6.4.1 Work environment
The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.
If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor
and control the work environment.
The organization shall:
a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;
b) ensure that all personnel who are required to work temporarily under special environmental

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
that we will have a flood

Further Action Required on Issue
0

	conditions within the work environment are competent or supervised by a competent person. NOTE Further information can be found in ISO 14644 and ISO 14698	

Process #6861 Management Meeting Review Weekly Meeting Non Minuted Management discussions on issues Updated On : 13 Nov 2021 Risks to the Process the meeting wont be held	Viamed Ltd ISO13485:2016 4.2.1 General Documentation requirements The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	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 the meeting wont be held Further Action Required on Issue 0

Process #6866 Internal Process Verification Complete Systems Review Review the Internal Process and Verification`s are suitable for the current standards  PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20 Updated On : 03 Nov 2021 Scope Review the Internal Process and Verification`s are suitable for the current standards PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20	Viamed Ltd ISO13485:2016 4.2.1 General Documentation requirements The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	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 Review not carried out Further Action Required on Issue 0

Process #6866 Internal Process Verification Complete Systems Review Review the Internal Process and Verification`s are suitable for the current standards PROCESS NOW	Viamed Ltd ISO13485:2016 8.5.3 Preventive action The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their	Does Update Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required:	Notes On Risk / Benefits statement if required Review not carried out

CANCELLED AS REPEAT OF AUDIT 20 Updated On : 03 Nov 2021 Scope Review the Internal Process and Verification`s are suitable for the current standards PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20	occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; e) reviewing the effectiveness of the preventive action taken, as appropriate. Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).	No Action Required	Further Action Required on Issue 0

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
Updated On : 12 Nov 2021
Scope
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

Viamed Ltd
ISO13485:2016
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 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

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
Opera and Intrastats go out of sync

Further Action Required on Issue
0

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.

Process #7070
Management Review
To discuss any problems, to assess work load and staffing.
To review issues.
Updated On : 02 Nov 2021
Training Method Required
Meeting agenda with the ISO Route Map. Hands on with the managing Director

Viamed Ltd
ISO13485:2016
4.2.1 General Documentation requirements
The quality management system documentation (see 4.2.4) shall include:
a) documented statements of a quality policy and quality objectives;
b) a quality manual;
c) documented procedures and records required by this International Standard;
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

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
Meetings not carried out regularly.
Further Action Required on Issue
0

e) other documentation specified by applicable regulatory requirements.

Process #7070
Management Review
To discuss any problems, to assess work load and staffing.
To review issues.
Updated On : 02 Nov 2021
Training Method Required
Meeting agenda with the ISO Route Map. Hands on with the managing Director

Viamed Ltd
ISO13485:2016
5.1 Management commitment
Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:
a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;
b) establishing the quality policy;
c) ensuring that quality objectives are established;
d) conducting management reviews;
e) ensuring the availability of resources.

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
Meetings not carried out regularly.
Further Action Required on Issue
0

Process #7070
Management Review
To discuss any problems, to assess work load and staffing.

Viamed Ltd
ISO13485:2016
5.6.1 General
The organization shall

Does Update Affect?
No
Risk Freqency due to Update

Notes On Risk / Benefits statement if required

To review issues.
Updated On : 02 Nov 2021
Training Method Required
Meeting agenda with the ISO Route Map. Hands on with the managing Director

document procedures for management review. Top management shall review
the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained

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

Meetings not carried out regularly.

Further Action Required on Issue
0

Process #7070
Management Review
To discuss any problems, to assess work load and staffing.
To review issues.
Updated On : 02 Nov 2021
Training Method Required
Meeting agenda with the ISO Route Map. Hands on with the managing

Viamed Ltd
ISO13485:2016
5.6.2 Review input General
The input to management review shall include, but is not limited to, information arising from:
a) feedback;
b) complaint handling;
c) reporting to regulatory authorities;

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
Meetings not carried out regularly.

Further Action Required on Issue
0

Director	d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.

Process #7070
Management Review
To discuss any problems, to assess work load and staffing.
To review issues.
Updated On : 02 Nov 2021
Training Method Required
Meeting agenda with the ISO Route Map. Hands on with the managing Director

Viamed Ltd
ISO13485:2016
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.

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
Meetings not carried out regularly.

Further Action Required on Issue
0

This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.

Process #7070
Management Review
To discuss any problems, to assess work load and staffing.
To review issues.
Updated On : 02 Nov 2021
Training Method Required
Meeting agenda with the ISO Route Map. Hands on with the managing Director

VST Ltd ISO9001:2015 9.3.2 Management review inputs
9.3.2 Management review inputs
The management review shall be planned and carried out taking into consideration:
a) the status of actions from previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:
1) customer satisfaction and feedback from relevant interested parties;
2) the extent to which quality objectives have been met;
3) process performance

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
Meetings not carried out regularly.

Further Action Required on Issue
0

and conformity of products and services;
4) nonconformities and corrective actions;
5) monitoring and measurement results;
6) audit results;
7) the performance of external providers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.

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
Updated On : 19 Nov 2021
Scope
Checking the Catalog 360 Circle website for outstanding orders or requests

SYSTEM NO LONGER USED

Viamed Ltd ISO13485:2016 7.2.3 Communication
The organization shall plan and document arrangements for communicating with customers in relation to:
a) product information;
b) enquiries, contracts or order handling, including amendments;
c) customer feedback, including complaints;
d) advisory notices.
The organization shall communicate with regulatory authorities in accordance with

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
Computer/network breakdown

Further Action Required on Issue
0

applicable
regulatory requirements.

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
Updated On : 19 Nov 2021

Scope

Checking the Catalog 360 Circle website for outstanding orders or requests

SYSTEM NO LONGER USED

VST Ltd ISO9001:2015 4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:
a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.
The organization shall monitor and review information about these interested parties and their
relevant requirements.

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
Computer/network breakdown

Further Action Required on Issue
0

Process #7678 Check Catalog 360 Circle For Quotes And Orders

VST Ltd ISO9001:2015 5.1.2 Customer focus

Does Update Affect?
No

Notes On Risk / Benefits statement if required

Checking the Catalog 360 Circle website for outstanding orders or requests

SYSTEM NO LONGER USED

Updated On : 19 Nov 2021

Scope

Checking the Catalog 360 Circle website for outstanding orders or requests

SYSTEM NO LONGER USED

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, 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.

Risk Freqency due to Update

1.Improbable

Risk Likly Due to Update

2.Minor

Action Required:

No Action Required

Computer/network breakdown

Further Action Required on Issue

0

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

Updated On : 19 Nov 2021

VST Ltd ISO9001:2015 6.2.1

The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

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

Computer/network breakdown

Further Action Required on Issue

0

Scope
Checking the Catalog 360 Circle website for outstanding orders or requests

SYSTEM NO LONGER USED

a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.
The organization shall maintain documented information on the quality objectives

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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

Updated On : 19 Nov 2021

Scope
Checking the Catalog 360 Circle website for outstanding orders or requests

SYSTEM NO LONGER

VST Ltd ISO9001:2015 7.5.1 General
Checking the Catalog 360 7.5.1 General
The organization's quality management system shall include:
a) documented information required by this International Standard;
b) documented information determined by the organization as being necessary for the effectiveness
of the quality management system.
NOTE The extent of documented information

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
Computer/network breakdown

Further Action Required on Issue
0

USED	for a quality management system can differ from one organization to another due to: ����the size of organization and its type of activities, processes, products and services; ����the complexity of processes and their interactions; � the competence of persons.

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 Updated On : 19 Nov 2021 Scope Checking the Catalog 360 Circle website for outstanding orders or requests SYSTEM NO LONGER USED	VST Ltd ISO9001:2015 8.2.1 Customer communication Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	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 Computer/network breakdown Further Action Required on Issue 0

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
Updated On : 19 Nov 2021
Scope
Checking the Catalog 360 Circle website for outstanding orders or requests

SYSTEM NO LONGER USED

VST Ltd ISO9001:2015 8.2.3 Review of the requirements for products and services

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
Computer/network breakdown

Further Action Required on Issue
0

Process #7684 Repairs Ready For Quote
Process Repairs Ready For Quote
Updated On : 12 Nov 2021
Risks to the Process
If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

Viamed Ltd ISO13485:2016 7.5.10 Customer property
The organization shall identify, verify, protect, and safeguard customer property provided for use
or incorporation into the product while it is under the organization's control or being used by the

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
If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

Further Action Required on Issue
0

	organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).		

Process #7684 Repairs Ready For Quote Process Repairs Ready For Quote Updated On : 12 Nov 2021 Risks to the Process If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods	Viamed Ltd ISO13485:2016 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	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 If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods Further Action Required on Issue 0

containers;
b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.
If special conditions are required, they shall be controlled and recorded (see 4.2.5).

Process #7684 Repairs Ready For Quote
Process Repairs Ready For Quote
Updated On : 12 Nov 2021
Risks to the Process
If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

VST Ltd ISO9001:2015
4.2 Understanding the needs and expectations of interested parties
Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:
a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.
The organization shall monitor and review

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
If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

Further Action Required on Issue
0

	information about these interested parties and their relevant requirements.		

Process #7684 Repairs Ready For Quote Process Repairs Ready For Quote Updated On : 12 Nov 2021 Risks to the Process If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods	VST Ltd ISO9001:2015 5.1.2 Customer focus 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, 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.	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 If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods Further Action Required on Issue 0

Process #7684 Repairs Ready For Quote Process Repairs Ready	VST Ltd ISO9001:2015 6.2.1	Does Update Affect? No	Notes On Risk / Benefits statement if required

For Quote
Updated On : 12 Nov 2021
Risks to the Process
If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

The organization shall establish quality objectives at relevant functions, levels and processes
needed for the quality management system.
The quality objectives shall:
a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.
The organization shall maintain documented information on the quality objectives

Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

Further Action Required on Issue
0

Process #7684 Repairs Ready For Quote
Process Repairs Ready For Quote
Updated On : 12 Nov 2021
Risks to the Process
If process does not get performed, we likly to loose customers,
get complaints over not

VST Ltd ISO9001:2015 7.5.1 General
7.5.1 General
The organization's quality management system shall include:
a) documented information required by this International Standard;

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:

Notes On Risk / Benefits statement if required

If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

responding to customers returned goods	b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management system can differ from one organization to another due to: ����the size of organization and its type of activities, processes, products and services; ����the complexity of processes and their interactions; ﷺ the competence of persons.	No Action Required	Further Action Required on Issue 0

Process #7684 Repairs Ready For Quote Process Repairs Ready For Quote Updated On : 12 Nov 2021 Risks to the Process If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods	VST Ltd ISO9001:2015 8.2.1 Customer communication Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services,	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 If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods Further Action Required on Issue 0

including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

Process #7684 Repairs Ready For Quote
Process Repairs Ready For Quote
Updated On : 12 Nov 2021
Risks to the Process
If process does not get performed, we likly to loose customers,
get complaints over not responding to customers returned goods

VST Ltd ISO9001:2015 8.2.3.1
The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:
a) requirements specified by the customer, including the requirements for delivery and postdelivery activities;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) requirements specified by the organization;

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
If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods

Further Action Required on Issue
0

d) statutory and regulatory requirements applicable to the products and services;
e) contract or order requirements differing from those previously expressed.
The organization shall ensure that contract or order requirements differing from those previously defined are resolved.
The customers requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.
NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

Process #7684 Repairs Ready For Quote Process Repairs Ready For Quote Updated On : 12 Nov 2021	VST Ltd ISO9001:2015 8.7.1 The organization shall ensure that outputs that do not conform to their	Does Update Affect? No Risk Freqency due to Update 1.Improbable	Notes On Risk / Benefits statement if required

Risks to the Process If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods	requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways: a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.	Risk Likly Due to Update 1.Negligible Action Required: No Action Required	If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods Further Action Required on Issue 0

Process #7685 Repairs Ready For Invoice
Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process repair has errors on it

Viamed Ltd
ISO13485:2016
7.5.10 Customer property
The organization shall identify, verify, protect, and safeguard customer property provided for use
or incorporation into the product while it is under the organization's control or being used by the
organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the
organization shall report this to the customer and maintain records (see 4.2.5).

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
repair has errors on it
Further Action Required on Issue
0

Process #7685 Repairs Ready For Invoice
Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process repair has errors on it

Viamed Ltd
ISO13485:2016
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

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
repair has errors on it
Further Action Required on Issue
0

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

Process #7685 Repairs Ready For Invoice
Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process
repair has errors on it

VST Ltd ISO9001:2015 4.2 Understanding the needs and expectations of interested parties
Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:

Notes On Risk / Benefits statement if required
repair has errors on it

customer and applicable statutory and regulatory requirements, the organization
shall determine:
a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.
The organization shall monitor and review information about these interested parties and their
relevant requirements.

No Action Required

Further Action Required on Issue
0

Process #7685 Repairs Ready For Invoice
Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process
repair has errors on it

VST Ltd ISO9001:2015 5.1.2 Customer focus
5.1.2 Customer focus
Top management shall demonstrate leadership and commitment with respect to customer focus by
ensuring that:
a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
b) the risks and opportunities that can

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
repair has errors on it

Further Action Required on Issue
0

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.

Process #7685 Repairs Ready For Invoice
Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process
repair has errors on it

VST Ltd ISO9001:2015 6.2.1
The organization shall establish quality objectives at relevant functions, levels and processes
needed for the quality management system.
The quality objectives shall:
a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.
The organization shall

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
repair has errors on it

Further Action Required on Issue
0

maintain documented information on the quality objectives

Process #7685 Repairs Ready For Invoice
Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process
repair has errors on it

VST Ltd ISO9001:2015
7.5.1 General
7.5.1 General
The organization's quality management system shall include:
a) documented information required by this International Standard;
b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.
NOTE The extent of documented information for a quality management system can differ from one organization to another due to:
- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

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
repair has errors on it

Further Action Required on Issue
0

Process #7685 Repairs Ready For Invoice Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process repair has errors on it

VST Ltd ISO9001:2015 8.2.1 Customer communication Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

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
repair has errors on it

Further Action Required on Issue
0

Process #7685 Repairs Ready For Invoice Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process repair has errors on it

VST Ltd ISO9001:2015 8.2.3 Review of the requirements for products and services

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
repair has errors on it

Further Action Required on Issue
0

Process #7685 Repairs Ready For Invoice
Process Invoice for completed repairs.
Updated On : 02 Nov 2021
Risks to the Process
repair has errors on it

VST Ltd ISO9001:2015 8.7.1
The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.
The organization shall take appropriate action based on the nature of the nonconformity and its effect
on the conformity of products and services.
This shall also apply to nonconforming products and
services detected after delivery of products, during or after the provision of services.
The organization shall deal with nonconforming outputs in one or more of the following ways:
a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under

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
repair has errors on it

Further Action Required on Issue
0

concession.
Conformity to the requirements shall be verified when nonconforming outputs are corrected.

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process
paperwork has been missed

Viamed Ltd ISO13485:2016
7.5.10 Customer property
The organization shall identify, verify, protect, and safeguard customer property provided for use
or incorporation into the product while it is under the organization's control or being used by the
organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the
organization shall report this to the customer and maintain records (see 4.2.5).

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
paperwork has been missed

Further Action Required on Issue
0

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov

VST Ltd ISO9001:2015
4.2 Understanding the needs and expectations of interested parties
Due to their effect or

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable

Notes On Risk / Benefits statement if required

2021
Risks to the Process
paperwork has been missed

potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:
a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.
The organization shall monitor and review information about these interested parties and their relevant requirements.

Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

paperwork has been missed

Further Action Required on Issue
0

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process
paperwork has been missed

VST Ltd ISO9001:2015 4.4.2 Quality management system and its processes
To the extent necessary, the organization shall:
a) maintain documented information to support the operation of its processes;
b) retain documented information to have

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
paperwork has been missed

Further Action Required on Issue
0

confidence that the processes are being carried out as planned.

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process
paperwork has been missed

VST Ltd ISO9001:2015 5.1.2 Customer focus
5.1.2 Customer focus
Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:
a) customer and applicable statutory and regulatory requirements are determined, 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.

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
paperwork has been missed

Further Action Required on Issue
0

Process #7693 Collect Repair Filing From Warehouse

VST Ltd ISO9001:2015 6.2.1

Does Update Affect?
No

Notes On Risk / Benefits statement if required

Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process paperwork has been missed

The organization shall establish quality objectives at relevant functions, levels and processes
needed for the quality management system.
The quality objectives shall:
a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.
The organization shall maintain documented information on the quality objectives

Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

paperwork has been missed

Further Action Required on Issue
0

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process paperwork has been missed

VST Ltd ISO9001:2015 7.1.5.2 Measurement traceability
When measurement traceability is a requirement, or is considered by the organization to be an essential
part of providing

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:

Notes On Risk / Benefits statement if required

paperwork has been missed

confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine their status; c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary	No Action Required	Further Action Required on Issue 0

Process #7693 Collect Repair Filing From	VST Ltd ISO9001:2015	Does Update Affect?	Notes On Risk / Benefits statement if required

Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process paperwork has been missed

7.5.1 General

7.5.1 General
The organization's quality management system shall include:
a) documented information required by this International Standard;
b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.
NOTE The extent of documented information for a quality management system can differ from one organization to another due to:
- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

No

Risk Freqency due to Update

1.Improbable

Risk Likly Due to Update

1.Negligible

Action Required: No Action Required

paperwork has been missed

Further Action Required on Issue

0

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse

VST Ltd ISO9001:2015
7.5.3.1
Documented information required by the quality

Does Update Affect?

No

Risk Freqency due to Update

Notes On Risk / Benefits statement if required

Updated On : 13 Nov 2021
Risks to the Process
paperwork has been missed

management system and by this International Standard shall be controlled to ensure:
a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

paperwork has been missed

Further Action Required on Issue
0

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process
paperwork has been missed

VST Ltd ISO9001:2015 7.5.3.2
For the control of documented information, the organization shall address the following activities, as applicable:
a) distribution, access, retrieval and use;
b) storage and preservation, including preservation of legibility;
c) control of changes (e.g. version control);
d) retention and disposition.
Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as

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
paperwork has been missed

Further Action Required on Issue
0

appropriate, and
be controlled.
Documented information retained as evidence of conformity shall be protected from unintended alterations.
NOTE Access can imply a decision regarding the permission to view the documented information only, or
the permission and authority to view and change the documented information.

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process
paperwork has been missed

VST Ltd ISO9001:2015
8.2.1 Customer communication
Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific

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
paperwork has been missed

Further Action Required on Issue
0

requirements for contingency actions, when relevant.

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process paperwork has been missed

VST Ltd ISO9001:2015 8.2.3 Review of the requirements for products and services

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
paperwork has been missed

Further Action Required on Issue
0

Process #7693 Collect Repair Filing From Warehouse
Collect the filing form the warehouse
Updated On : 13 Nov 2021
Risks to the Process paperwork has been missed

VST Ltd ISO9001:2015 9.1.1 General
The organization shall determine:
a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analysed and evaluated.
The organization shall evaluate the performance

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
paperwork has been missed

Further Action Required on Issue
0

	and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results.		

Process #7693 Collect Repair Filing From Warehouse Collect the filing form the warehouse Updated On : 13 Nov 2021 Risks to the Process paperwork has been missed	VST Ltd ISO9001:2015 9.1.2 Customer satisfaction The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.	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 paperwork has been missed Further Action Required on Issue 0

Process #7703
Vandagraph Pay Pal Retrieve Funds
To remove money from the Pay Pal system into Vandagraph Bank account
Updated On : 13 Nov 2021
Input to the Process
PayPal

VST Ltd ISO9001:2015 8.2.1 Customer communication
Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

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
No risk to the process as such as its paypal driven,
Can only withdraw funds to allocated bank account

Further Action Required on Issue
0

Process #7703
Vandagraph Pay Pal Retrieve Funds
To remove money from the Pay Pal system into Vandagraph Bank account
Updated On : 13 Nov 2021
Input to the Process
PayPal

VST Ltd ISO9001:2015 8.2.2 Determining the requirements for products and services
When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:
a) the requirements for the products and services

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
No risk to the process as such as its paypal driven,
Can only withdraw funds to allocated bank account

Further Action Required on Issue
0

	are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers.	

Process #7709 Delivered not Invoiced Ensure invoices are generated for shipped orders Updated On : 02 Nov 2021 Steps to Minimise Process Risks regular review of tasks / issues	VST Ltd ISO9001:2015 4.2 Understanding the needs and expectations of interested parties Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system. The organization shall monitor and review	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

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Computer/network breakdown
delivery is missed and remains un invoiced.
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Further Action Required on Issue

0

information about these interested parties and their relevant requirements.

Process #7709 Delivered not Invoiced
Ensure invoices are generated for shipped orders
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
regular review of tasks / issues

VST Ltd ISO9001:2015 5.1.2 Customer focus
5.1.2 Customer focus
Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:
a) customer and applicable statutory and regulatory requirements are determined, 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.

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
Computer/network breakdown
delivery is missed and remains un invoiced.

Further Action Required on Issue
0

Process #7709 Delivered not Invoiced
Ensure invoices are

VST Ltd ISO9001:2015 6.2.1

Does Update Affect?
No

Notes On Risk / Benefits statement if required

generated for shipped orders
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
regular review of tasks / issues

The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.
The quality objectives shall:
a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.
The organization shall maintain documented information on the quality objectives

Risk Freqency due to Update: 2.Remote
Risk Likly Due to Update: 2.Minor
Action Required: No Action Required

Computer/network breakdown
delivery is missed and remains un invoiced.

Further Action Required on Issue: 0

Process #7709 Delivered not Invoiced
Ensure invoices are generated for shipped orders
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
regular review of tasks / issues

VST Ltd ISO9001:2015 7.5.1 General
7.5.1 General
The organization's quality management system shall include:
a) documented information required by this International Standard;

Does Update Affect?: No
Risk Freqency due to Update: 2.Remote
Risk Likly Due to Update: 2.Minor
Action Required:

Notes On Risk / Benefits statement if required

Computer/network breakdown
delivery is missed and remains un invoiced.

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.
NOTE The extent of documented information for a quality management system can differ from one organization to another due to:
- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

No Action Required

Further Action Required on Issue
0

Process #7709 Delivered not Invoiced
Ensure invoices are generated for shipped orders
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
regular review of tasks / issues

VST Ltd ISO9001:2015 8.2.1 Customer communication
Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services,

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
Computer/network breakdown
delivery is missed and remains un invoiced.

Further Action Required on Issue
0

including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

Process #7709 Delivered not Invoiced
Ensure invoices are generated for shipped orders
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
regular review of tasks / issues

VST Ltd ISO9001:2015
8.2.3 Review of the requirements for products and services

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
Computer/network breakdown
delivery is missed and remains un invoiced.

Further Action Required on Issue
0

Process #7713 Review Roles And Responsibilitys
Ensure All tasks allocated to active Members of staff,

Updated On : 11 Nov 2021
Risk/Benefit Report if applicable

Viamed Ltd ISO13485:2016
4.2.1 General Documentation requirements
The quality management system documentation (see 4.2.4) shall include:
a) documented statements of a quality policy and quality objectives;
b) a quality manual;

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
That not all jobs will be allocated to a member of staff.
That we may not share out jobs in a appropriate way.
Risk of being over faced.

Further Action Required on Issue
0

c) documented procedures and records required by this International Standard;
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;
e) other documentation specified by applicable regulatory requirements.

Process #7713 Review Roles And Responsibilitys
Ensure All tasks allocated to active Members of staff,

Updated On : 11 Nov 2021
Risk/Benefit Report if applicable

Viamed Ltd ISO13485:2016 5.5.1 Responsibility and authority
Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.
Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

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
That not all jobs will be allocated to a member of staff.
That we may not share out jobs in a appropriate way.
Risk of being over faced.

Further Action Required on Issue
0

Process #7713 Review Roles And Responsibilitys
Ensure All tasks allocated to active Members of staff,

Updated On : 11 Nov 2021
Risk/Benefit Report if applicable

Viamed Ltd ISO13485:2016
5.6.2 Review input
General
The input to management review shall include, but is not limited to, information arising from:
a) feedback;
b) complaint handling;
c) reporting to regulatory authorities;
d) audits;
e) monitoring and measurement of processes;
f) monitoring and measurement of product;
g) corrective action;
h) preventive action;
i) follow-up actions from previous management reviews;
j) changes that could affect the quality management system;
k) recommendations for improvement;
l) applicable new or revised regulatory requirements.

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
That not all jobs will be allocated to a member of staff.
That we may not share out jobs in a appropriate way.
Risk of being over faced.

Further Action Required on Issue
0

Process #7713 Review Roles And Responsibilitys
Ensure All tasks allocated to active Members of

Viamed Ltd ISO13485:2016
6.3 Infrastructure
The organization shall

Does Update Affect?
No
Risk Freqency due to Update

Notes On Risk / Benefits statement if required

staff, Updated On : 11 Nov 2021 Risk/Benefit Report if applicable	document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.	2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Further Action Required on Issue 0

Records of such maintenance shall be maintained

Process #7713 Review Roles And Responsibilitys
Ensure All tasks allocated to active Members of staff,

Updated On : 11 Nov 2021
Risk/Benefit Report if applicable

VST Ltd ISO9001:2015 4.4.2 Quality management system and its processes
To the extent necessary, the organization shall:
a) maintain documented information to support the operation of its processes;
b) retain documented information to have confidence that the processes are being carried out as planned.

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
That not all jobs will be allocated to a member of staff.
That we may not share out jobs in a appropriate way.
Risk of being over faced.

Further Action Required on Issue 0

Process #7713 Review Roles And Responsibilitys
Ensure All tasks allocated to active Members of staff,

Updated On : 11 Nov 2021
Risk/Benefit Report if applicable

VST Ltd ISO9001:2015 7.1.2 People
The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

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
That not all jobs will be allocated to a member of staff.
That we may not share out jobs in a appropriate way.
Risk of being over faced.

Further Action Required on Issue 0

Process #7713 Review Roles And

VST Ltd ISO9001:2015

Does Update Affect?

Notes On Risk / Benefits statement if required

Responsibilitys
Ensure All tasks allocated to active Members of staff,

Updated On : 11 Nov 2021
Risk/Benefit Report if applicable

9.1.3 Analysis and evaluation
The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.
The results of analysis shall be used to evaluate:
a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.
NOTE Methods to analyse data can include statistical techniques.

No
Risk Freqency due to Update
2.Remote
Risk Likly Due to Update
2.Minor
Action Required:
No Action Required

That not all jobs will be allocated to a member of staff.
That we may not share out jobs in a appropriate way.
Risk of being over faced.

Further Action Required on Issue
0

Process #7713 Review Roles And Responsibilitys
Ensure All tasks allocated to active Members of staff,

VST Ltd ISO9001:2015
9.3.2 Management review inputs
9.3.2 Management review inputs

Does Update Affect?
No
Risk Freqency due to Update
2.Remote

Notes On Risk / Benefits statement if required

Updated On : 11 Nov 2021 Risk/Benefit Report if applicable	The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) information on the performance and effectiveness of the quality management system, including trends in: 1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address	Risk Likly Due to Update 2.Minor Action Required: No Action Required	That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Further Action Required on Issue 0

	risks and opportunities (see 6.1); f) opportunities for improvement.		

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. Updated On : 02 Nov 2021 Risks to the Process Customer Complaints could be missed or not filed correctly	Viamed Ltd ISO13485:2016 4.1.2 Quality management system The organization shall: a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization; b) apply a risk based approach to the control of the appropriate processes needed for the quality management system; c) determine the sequence and interaction of these processes.	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 Customer Complaints could be missed or not filed correctly Further Action Required on Issue 0

Process #7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file.	Viamed Ltd ISO13485:2016 5.2 Customer focus Top management shall ensure that customer	Does Update Affect? No Risk Freqency due to Update 1.Improbable	Notes On Risk / Benefits statement if required

Check the File is being Maintained and any relevant documentation is in the File.
Updated On : 02 Nov 2021
Risks to the Process Customer Complaints could be missed or not filed correctly

requirements and applicable regulatory requirements are determined and met.

Risk Likly Due to Update
2.Minor
Action Required:
No Action Required

Customer Complaints could be missed or not filed correctly

Further Action Required on Issue
0

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.
Updated On : 02 Nov 2021
Risks to the Process Customer Complaints could be missed or not filed correctly

Viamed Ltd ISO13485:2016 5.6.2 Review input General
The input to management review shall include, but is not limited to, information arising from:
a) feedback;
b) complaint handling;
c) reporting to regulatory authorities;
d) audits;
e) monitoring and measurement of processes;
f) monitoring and measurement of product;
g) corrective action;
h) preventive action;
i) follow-up actions from previous management reviews;
j) changes that could

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
Customer Complaints could be missed or not filed correctly

Further Action Required on Issue
0

affect the quality management system;
k) recommendations for improvement;
l) applicable new or revised regulatory requirements.

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.
Updated On : 02 Nov 2021
Risks to the Process Customer Complaints could be missed or not filed correctly

Viamed Ltd ISO13485:2016 7.2.3 Communication
The organization shall plan and document arrangements for communicating with customers in relation to:
a) product information;
b) enquiries, contracts or order handling, including amendments;
c) customer feedback, including complaints;
d) advisory notices.
The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

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
Customer Complaints could be missed or not filed correctly

Further Action Required on Issue
0

Process #7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file.

Viamed Ltd ISO13485:2016 8.2.2 Complaint handling
The organization shall

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable

Notes On Risk / Benefits statement if required

Check the File is being Maintained and any relevant documentation is in the File. Updated On : 02 Nov 2021 Risks to the Process Customer Complaints could be missed or not filed correctly	document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for: a) receiving and recording information; b) evaluating information to determine if the feedback constitutes a complaint; c) investigating complaints; d) determining the need to report the information to the appropriate regulatory authorities; e) handling of complaint-related product; f) determining the need to initiate corrections or corrective actions. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the complaint handling process shall be documented. If an investigation determines activities	Risk Likly Due to Update 2.Minor Action Required: No Action Required	Customer Complaints could be missed or not filed correctly Further Action Required on Issue 0

	outside the organization contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Complaint handling records shall be maintained (see 4.2.5).	

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. Updated On : 02 Nov 2021 Risks to the Process Customer Complaints could be missed or not filed correctly	Viamed Ltd ISO13485:2016 8.2.3 Reporting to regulatory authorities If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization shall document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities shall be maintained (see 4.2.5).	Does 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 Customer Complaints could be missed or not filed correctly Further Action Required on Issue 0

Process #7743 Customer Complaints Paper File Major Customer Complaints get escalated	Viamed Ltd ISO13485:2016 8.3.1 General	Does Update Affect? No Risk Freqency	Notes On Risk / Benefits statement if required

to Paper Customer Complaints file. Check the File is being Maintained and any relevant documentation is in the File. Updated On : 02 Nov 2021 Risks to the Process Customer Complaints could be missed or not filed correctly	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)	due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Customer Complaints could be missed or not filed correctly Further Action Required on Issue 0

Process #7743 Customer	Does Update	Notes On Risk / Benefits statement if required

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. Updated On : 02 Nov 2021 Risks to the Process Customer Complaints could be missed or not filed correctly	Viamed Ltd ISO13485:2016 8.5.3 Preventive action The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;	Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Customer Complaints could be missed or not filed correctly Further Action Required on Issue 0

e) reviewing the effectiveness of the preventive action taken, as appropriate.
Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

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.
Updated On : 02 Nov 2021
Risks to the Process Customer Complaints could be missed or not filed correctly

VST Ltd ISO9001:2015 5.1.1 General
Top management shall demonstrate leadership and commitment with respect to the quality management system by:
a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization's business processes;
d) promoting the use of the process approach and

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
Customer Complaints could be missed or not filed correctly

Further Action Required on Issue
0

risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the

organization is public, private,
for profit or not for profit.

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.
Updated On : 02 Nov 2021
Risks to the Process Customer Complaints could be missed or not filed correctly

VST Ltd ISO9001:2015 9.1.3 Analysis and evaluation
The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.
The results of analysis shall be used to evaluate:
a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.
NOTE Methods to analyse data can include statistical techniques.

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
Customer Complaints could be missed or not filed correctly

Further Action Required on Issue
0

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.

Updated On : 02 Nov 2021

Risks to the Process

Customer Complaints could be missed or not filed correctly

VST Ltd ISO9001:2015 9.3.2 Management review inputs

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties;

2) the extent to which quality objectives have been met;

3) process performance and conformity of products and services;

4) nonconformities and corrective actions;

5) monitoring and measurement results;

6) audit results;

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

Customer Complaints could be missed or not filed correctly

Further Action Required on Issue

0

7) the performance of external providers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.

Process #7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products

In order to sell in the USA / Canada Markets products need to be registered with the FDA.

Updated On : 02 Nov 2021

Training Method Required
Hands on Learning from experienced staff

VST Ltd ISO9001:2015 4.3 Determining the scope of the quality management system
The organization shall determine the boundaries and applicability of the quality management system
to establish its scope.
When determining this scope, the organization shall consider:
a) the external and internal issues referred to in 4.1;
b) the requirements of relevant interested parties referred to in 4.2;
c) the products and services of the organization.
The organization shall apply all the requirements of this International Standard if they are applicable

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

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Its harder to initially get on teh register than maintaining it.

Inability to sell products in North America
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Further Action Required on Issue
0

within the determined scope of its quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

Process #7744 FDA Device Establishment Registration And Listing	VST Ltd ISO9001:2015 5.1.1 General	Does Update Affect? No	Notes On Risk / Benefits statement if required

FDA registration and the CMDCAS products

In order to sell in the USA / Canada Markets products need to be registered with the FDA.

Updated On : 02 Nov 2021
Training Method Required
Hands on Learning from experienced staff

Top management shall demonstrate leadership and commitment with respect to the quality management system by:
a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization's business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;

Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

Its harder to initially get on teh register than maintaining it.

Inability to sell products in North America

Further Action Required on Issue
0

g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

Process #7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products In order to sell in the	VST Ltd ISO9001:2015 5.3 Organizational roles, responsibilities and authorities Top management shall ensure that the	Does Update Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required

USA / Canada Markets products need to be registered with the FDA. Updated On : 02 Nov 2021 Training Method Required Hands on Learning from experienced staff	responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management shall assign the responsibility and authority for: a) ensuring that the quality management system conforms to the requirements of this International Standard; b) ensuring that the processes are delivering their intended outputs; c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management; d) ensuring the promotion of customer focus throughout the organization; e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	to Update 1.Negligible Action Required: No Action Required	Its harder to initially get on teh register than maintaining it. Inability to sell products in North America Further Action Required on Issue 0

Process #7744 FDA	Does Update	Notes On Risk / Benefits statement if required

Device Establishment Registration And Listing FDA registration and the CMDCAS products

In order to sell in the USA / Canada Markets products need to be registered with the FDA.

Updated On : 02 Nov 2021

Training Method Required

Hands on Learning from experienced staff

VST Ltd ISO9001:2015 7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been

Affect?

No

Risk Freqency due to Update

1.Improbable

Risk Likly Due to Update

1.Negligible

Action Required:

No Action Required

Its harder to initially get on teh register than maintaining it.

Inability to sell products in North America

Further Action Required on Issue

0

adversely
affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary

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Process #7744 FDA Device Establishment Registration And Listing

FDA registration and the CMDCAS products

In order to sell in the USA / Canada Markets products need to be registered with the FDA.

Updated On : 02 Nov 2021

Training Method Required

Hands on Learning from experienced staff

VST Ltd ISO9001:2015 7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to
achieve conformity of products and services.
This knowledge shall be maintained and be made available to the extent necessary.
When addressing changing needs and trends, the organization shall consider its current knowledge
and determine how to acquire or access any necessary additional knowledge and required updates.
NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is

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

Its harder to initially get on teh register than maintaining it.

Inability to sell products in North America

Further Action Required on Issue

0

information that is used and shared to achieve the organization's objectives.
NOTE 2 Organizational knowledge can be based on:
a)internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
b)external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)

Process #7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products

In order to sell in the USA / Canada Markets products need to be registered with the FDA.

VST Ltd ISO9001:2015 7.5.1 General
7.5.1 General
The organization's quality management system shall include:
a) documented information required by this International Standard;

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:

Notes On Risk / Benefits statement if required
Its harder to initially get on teh register than maintaining it.

Inability to sell products in North America

Further Action Required on Issue
0

Updated On : 02 Nov 2021 Training Method Required Hands on Learning from experienced staff	b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management system can differ from one organization to another due to: ����the size of organization and its type of activities, processes, products and services; ����the complexity of processes and their interactions; • the competence of persons.	No Action Required

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Process #7744 FDA Device Establishment Registration And Listing

FDA registration and the CMDCAS products

In order to sell in the USA / Canada Markets products need to be registered with the FDA.

Updated On : 02 Nov 2021

Training Method

VST Ltd ISO9001:2015 7.5.3.1

Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality,

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

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Its harder to initially get on teh register than maintaining it.

Inability to sell products in North America
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Further Action Required on Issue

0

Required Hands on Learning from experienced staff	improper use, or loss of integrity).		

Process #7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products In order to sell in the USA / Canada Markets products need to be registered with the FDA. Updated On : 02 Nov 2021 Training Method Required Hands on Learning from experienced staff	VST Ltd ISO9001:2015 8.3.3 Design and development inputs The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and	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 Its harder to initially get on teh register than maintaining it. Inability to sell products in North America Further Action Required on Issue 0

unambiguous.
Conflicting design and development inputs shall be resolved.
The organization shall retain documented information on design and development inputs.

Process #7744 FDA Device Establishment Registration And Listing
FDA registration and the CMDCAS products

In order to sell in the USA / Canada Markets products need to be registered with the FDA.

Updated On : 02 Nov 2021
Training Method Required
Hands on Learning from experienced staff

VST Ltd ISO9001:2015 9.2.1
The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:
a) conforms to:
1) the organization's own requirements for its quality management system;
2) the requirements of this International Standard;
b) is effectively implemented and maintained.

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
Its harder to initially get on teh register than maintaining it.

Inability to sell products in North America

Further Action Required on Issue
0

Process #7784 Check Returns Supplier Envitec
Supplier returns to Envitec,
return any products waiting to be returned
Updated On : 03 Nov 2021

Viamed Ltd ISO13485:2016 7.4.2 Purchasing information
Purchasing information shall describe or reference the product to

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update

Notes On Risk / Benefits statement if required

Risks to the Process Product not returned so missing the supplier warranty	be purchased, including as appropriate: a) product specifications; 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	2.Minor Action Required: No Action Required	Product not returned so missing the supplier warranty Further Action Required on Issue 0

of documents (see 4.2.4) and records (see 4.2.5).

Process #7784 Check Returns Supplier Envitec
Supplier returns to Envitec,
return any products waiting to be returned
Updated On : 03 Nov 2021
Risks to the Process
Product not returned so missing the supplier warranty

VST Ltd ISO9001:2015 8.4.3 Information for external providers
The organization shall ensure the adequacy of requirements prior to their communication to the external provider.
The organization shall communicate to external providers its requirements for:
a) the processes, products and services to be provided;
b) the approval of:
1) products and services;
2) methods, processes and equipment;
3) the release of products and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with the organization;
e) control and monitoring of the external providers' performance to be applied by the organization;
f) verification or

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
Product not returned so missing the supplier warranty

Further Action Required on Issue
0

validation activities that the organization, or its customer, intends to perform at the external providers premises.

Process #7789 Withdraw Funds From Paypal
To remove the receipts that have come into Paypal over the month. So they can be entered in to accounts sales.
Updated On : 13 Nov 2021
Scope
To remove the receipts that have come into Paypal over the month. So they can be entered in to accounts sales.

VST Ltd ISO9001:2015
8.2.1 Customer communication
Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

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
That a payment is not entered accounts , or onto the correct sales account.
Further Action Required on Issue
0

Process #7791 Price List Check
Changing of the prices lists.
Issue to check these are current

VST Ltd ISO9001:2015
5.1.1 General
Top management shall demonstrate leadership and commitment with

Does Update Affect?
No
Risk Freqency due to Update
2.Remote

Notes On Risk / Benefits statement if required

*Vandagraph is not an ISO company
Updated On : 13 Nov 2021
Scope
Changing of the prices lists.
Issue to check these are current

*Vandagraph is not an ISO company

respect to the quality management system by:
a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization's business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its

Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

That people will quote the wrong price to the customer.

Further Action Required on Issue
0

intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

Process #7791 Price List Check
Changing of the prices lists.
Issue to check these are current

*Vandagraph is not an ISO company

VST Ltd ISO9001:2015 5.1.2 Customer focus
5.1.2 Customer focus
Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

Does Update Affect?
No
Risk Freqency due to Update
2.Remote
Risk Likly Due to Update

Notes On Risk / Benefits statement if required
That people will quote the wrong price to the customer.

Updated On : 13 Nov 2021
Scope
Changing of the prices lists.
Issue to check these are current

*Vandagraph is not an ISO company

a) customer and applicable statutory and regulatory requirements are determined, 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.

1.Negligible
Action Required:
No Action Required

Further Action Required on Issue
0

Process #7816 Repairs In Process Review
Review the Repairs In Process
Updated On : 13 Nov 2021
Scope
Review the Repairs In Process

VST Ltd ISO9001:2015 8.3.3 Design and development inputs
The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:
a) functional and performance requirements;
b) information derived from previous similar design and development

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
That the process is not updated and not as effective as it could be

Further Action Required on Issue
0

activities;
c) statutory and regulatory requirements;
d) standards or codes of practice that the organization has committed to implement;
e) potential consequences of failure due to the nature of the products and services.
Inputs shall be adequate for design and development purposes, complete and unambiguous.
Conflicting design and development inputs shall be resolved.
The organization shall retain documented information on design and development inputs.

Process #7823 Saftey Tester Data Backup the Fluke ESA615 Safety tester CE

Copy any files to the Z Drive - safety tester backupdata
Updated On : 02 Nov 2021
Training Method Required
Hands on Learning from experienced staff

VST Ltd ISO9001:2015 7.1.3 Infrastructure
The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.
NOTE Infrastructure can include:
a) buildings and associated utilities;

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
That this will not be carried out.
Further Action Required on Issue
0

b) equipment, including hardware and software;
c) transportation resources;
d) information and communication technology.

Process #7823 Saftey Tester Data Backup the Fluke ESA615 Safety tester CE

Copy any files to the Z Drive - safety tester backupdata
Updated On : 02 Nov 2021
Training Method Required
Hands on Learning from experienced staff

VST Ltd ISO9001:2015 7.1.5.2 Measurement traceability
When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:
a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
b) identified in order to determine their status;
c) safeguarded from

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
That this will not be carried out.

Further Action Required on Issue
0

adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.
The organization shall determine if the validity of previous measurement results has been adversely
affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary

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Process #7823 Saftey Tester Data Backup the Fluke ESA615 Safety tester CE

Copy any files to the Z Drive - safety tester backupdata
Updated On : 02 Nov 2021
Training Method Required
Hands on Learning from experienced staff

VST Ltd ISO9001:2015 8.4.3 Information for external providers
The organization shall ensure the adequacy of requirements prior to their communication to the
external provider.
The organization shall communicate to external providers its requirements for:
a) the processes, products and services to be provided;
b) the approval of:
1) products and services;
2) methods, processes and equipment;
3) the release of products

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
That this will not be carried out.
Further Action Required on Issue
0

and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with the organization;
e) control and monitoring of the external providers' performance to be applied by the organization;
f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

Process #7823 Saftey Tester Data Backup the Fluke ESA615 Safety tester CE

Copy any files to the Z Drive - safety tester backupdata
Updated On : 02 Nov 2021

Training Method Required
Hands on Learning from experienced staff

VST Ltd ISO9001:2015 8.5.3 Property belonging to customers or external providers

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.
The organization shall identify, verify, protect and safeguard

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
That this will not be carried out.

Further Action Required on Issue
0

customers’ or external providers’ property provided for use or incorporation into the products and services. 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. NOTE A customer’s or external provider’s property can include materials, components, tools and equipment, premises, intellectual property and personal data.

Process #7832
Cleardown Emailed Invoices
Backup of all Sent Emails sent to External Address for Verification
Updated On : 13 Nov 2021
Risks to the Process
that we may loose some emails

Viamed Ltd
ISO13485:2016
6.3 Infrastructure
The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling

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
that we may loose some emails

Further Action Required on Issue
0

of product.
Infrastructure includes, as appropriate:
a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).
The organization shall document requirements for the maintenance activities, including the interval
of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.
Records of such maintenance shall be maintained

Process #7832		Does Update	Notes On Risk / Benefits statement if required
Cleardown Emailed	VST Ltd ISO9001:2015	Affect?	
Invoices	6.1.2	No	
Backup of all Sent	The organization shall	Risk Freqency	

Emails sent to External Address for Verification Updated On : 13 Nov 2021 Risks to the Process that we may loose some emails	plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building	due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	that we may loose some emails Further Action Required on Issue 0

partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

Process #7832
Cleardown Emailed Invoices
Backup of all Sent Emails sent to External Address for Verification
Updated On : 13 Nov 2021
Risks to the Process
that we may loose some emails

VST Ltd ISO9001:2015
7.1.3 Infrastructure
The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.
NOTE Infrastructure can include:
a) buildings and associated utilities;
b) equipment, including hardware and software;
c) transportation resources;
d) information and communication technology.

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
that we may loose some emails
Further Action Required on Issue
0

Process #7835 Electrics Need Checking
To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety
Updated On : 02 Nov

Viamed Ltd
ISO13485:2016
6.3 Infrastructure
The organization shall document the requirements for the infrastructure needed to

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update

Notes On Risk / Benefits statement if required

2021 Input to the Process Electrician and the electrical regulations	achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained	1.Negligible Action Required: No Action Required	Not carried out in a timely manner Further Action Required on Issue 0

Process #7835 Electrics Need Checking
To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety
Updated On : 02 Nov 2021
Input to the Process
Electrician and the electrical regulations

Viamed Ltd
ISO13485:2016
6.4.1 Work environment
The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.
If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor
and control the work environment.
The organization shall:
a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;
b) ensure that all personnel who are required to work temporarily under special environmental

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
Not carried out in a timely manner

Further Action Required on Issue
0

conditions within the work environment are competent or supervised by a competent person.
NOTE Further information can be found in ISO 14644 and ISO 14698

Process #7835 Electrics Need Checking
To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety
Updated On : 02 Nov 2021
Input to the Process Electrician and the electrical regulations

VST Ltd ISO9001:2015
7.1.3 Infrastructure
The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.
NOTE Infrastructure can include:
a) buildings and associated utilities;
b) equipment, including hardware and software;
c) transportation resources;
d) information and communication technology.

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
Not carried out in a timely manner
Further Action Required on Issue
0

Process #7838 Review VIAMED Feedback - Customer Feedback Negative
Review Customer Feedback Negative

Viamed Ltd
ISO13485:2016
4.2.1 General Documentation requirements

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable

Notes On Risk / Benefits statement if required

Updated On : 02 Nov 2021
Steps to Minimise Process Risks
Regular review of the issues

The quality management system documentation (see 4.2.4) shall include:
a) documented statements of a quality policy and quality objectives;
b) a quality manual;
c) documented procedures and records required by this International Standard;
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;
e) other documentation specified by applicable regulatory requirements.

Risk Likly Due to Update
3.Serious
Action Required:
No Action Required

Rolling Issues No risk to process

Further Action Required on Issue
0

Process #7838 Review
VIAMED Feedback - Customer Feedback Negative
Review Customer Feedback Negative
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
Regular review of the issues

Viamed Ltd
ISO13485:2016
5.6.2 Review input General
The input to management review shall include, but is not limited to, information arising from:
a) feedback;
b) complaint handling;
c) reporting to regulatory authorities;
d) audits;
e) monitoring and

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
Rolling Issues No risk to process

Further Action Required on Issue
0

measurement of processes;
f) monitoring and measurement of product;
g) corrective action;
h) preventive action;
i) follow-up actions from previous management reviews;
j) changes that could affect the quality management system;
k) recommendations for improvement;
l) applicable new or revised regulatory requirements.

Process #7838 Review
VIAMED Feedback - Customer Feedback Negative
Review Customer Feedback Negative
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
Regular review of the issues

Viamed Ltd
ISO13485:2016
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

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
Rolling Issues No risk to process

Further Action Required on Issue
0

appropriate methods, including statistical techniques, and the extent of their use.

Process #7838 Review
VIAMED Feedback - Customer Feedback Negative
Review Customer Feedback Negative
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
Regular review of the issues

Viamed Ltd
ISO13485:2016
8.5.3 Preventive action
The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.
The organization shall document a procedure to describe requirements for:
a) determining potential nonconformities and their causes;
b) evaluating the need for action to prevent occurrence of nonconformities;
c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
d) verifying that the

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
Rolling Issues No risk to process

Further Action Required on Issue
0

action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
e) reviewing the effectiveness of the preventive action taken, as appropriate.
Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

Process #7838 Review VIAMED Feedback - Customer Feedback Negative
Review Customer Feedback Negative
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
Regular review of the issues

VST Ltd ISO9001:2015 5.1.2 Customer focus
5.1.2 Customer focus
Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:
a) customer and applicable statutory and regulatory requirements are determined, 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

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
Rolling Issues No risk to process
Further Action Required on Issue
0

addressed;
c) the focus on enhancing customer satisfaction is maintained.

Process #7838 Review VIAMED Feedback - Customer Feedback Negative
Review Customer Feedback Negative
Updated On : 02 Nov 2021
Steps to Minimise Process Risks
Regular review of the issues

VST Ltd ISO9001:2015 8.2.1 Customer communication
Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

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
Rolling Issues No risk to process
Further Action Required on Issue
0

Process #7838 Review VIAMED Feedback - Customer Feedback Negative
Review Customer Feedback Negative
Updated On : 02 Nov

VST Ltd ISO9001:2015 8.5.5 Post-delivery activities
The organization shall meet requirements for post-delivery activities

Does Update Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due

Notes On Risk / Benefits statement if required

2021 Steps to Minimise Process Risks Regular review of the issues	associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	to Update 3.Serious Action Required: No Action Required	Rolling Issues No risk to process Further Action Required on Issue 0

Process #7838 Review VIAMED Feedback - Customer Feedback Negative Review Customer Feedback Negative Updated On : 02 Nov	VST Ltd ISO9001:2015 9.1.2 Customer satisfaction The organization shall monitor customers' perceptions of the degree	Does Update Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required

2021
Steps to Minimise Process Risks
Regular review of the issues

to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.
NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

to Update
3.Serious
Action Required:
No Action Required

Rolling Issues No risk to process

Further Action Required on Issue
0

Process #7851 Software Validation Scan Un-QA Product To Order
To test intrastats does not allow picking of unprocessed products to live customer orders
Updated On : 23 Nov 2021
Risk/Benefit Report if applicable
Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA.
This process itself is to

Viamed Ltd
ISO13485:2016
4.1.6 Quality management system
For each quality management system process, the organization shall:
The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be

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
Unprocessed product gets out into the field, resulting in recalls
Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA.
This process itself is to reduce the risk of UN-QA product getting past goods out

Further Action Required on Issue
0

reduce the risk of UN-QA product getting past goods out	validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).

Process #7851 Software Validation Scan Un-QA Product To Order To test intrastats does not allow picking of unprocessed products to live customer orders Updated On : 23 Nov 2021 Risk/Benefit Report if applicable Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA. This process itself is to reduce the risk of UN-QA product getting past goods out	Viamed Ltd ISO13485:2016 6.3 Infrastructure The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport,	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 Unprocessed product gets out into the field, resulting in recalls Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA. This process itself is to reduce the risk of UN-QA product getting past goods out Further Action Required on Issue 0

communication, or information systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained

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Process #7851 Software Validation Scan Un-QA Product To Order

To test intrastats does not allow picking of unprocessed products to live customer orders

Updated On : 23 Nov 2021

Risk/Benefit Report if applicable

Likelihood is Improbable as this process tests the actual system of

Viamed Ltd ISO13485:2016 7.5.6 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring

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

Unprocessed product gets out into the field, resulting in recalls
Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA.
This process itself is to reduce the risk of UN-QA product getting past goods out

Further Action Required on Issue

0

preventing UN-QA stock getting past QA. This process itself is to reduce the risk of UN-QA product getting past goods out	or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes including: a) defined criteria for review and approval of the processes; b) equipment qualification and qualification of personnel; c) use of specific methods, procedures and acceptance criteria; d) as appropriate, statistical techniques with rationale for sample sizes e) requirements for records (see 4.2.5); f) revalidation, including criteria for revalidation; g) approval of changes to the processes. The organization shall document procedures for the validation of the

application of computer software
used in production and service provision. Such software applications shall be validated prior to initial
use and, as appropriate, after changes to such software or its application. The specific approach and
activities associated with software validation and revalidation shall be proportionate to the risk 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).

Process #7851 Software Validation Scan Un-QA Product To Order To test intrastats does not allow picking of unprocessed products to live customer orders Updated On : 23 Nov 2021	VST Ltd ISO9001:2015 7.1.3 Infrastructure The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to	Does Update Affect? No Risk Freqency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement if required

Risk/Benefit Report if applicable Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA. This process itself is to reduce the risk of UN-QA product getting past goods out	achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology.	1.Negligible Action Required: No Action Required	Unprocessed product gets out into the field, resulting in recalls Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA. This process itself is to reduce the risk of UN-QA product getting past goods out Further Action Required on Issue 0

Process #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. Updated On : 02 Nov 2021 Risks to the Process issues not carried out	Viamed Ltd ISO13485:2016 4.1.6 Quality management system For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation	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 issues not carried out Further Action Required on Issue 0

and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).

Process #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.
Updated On : 02 Nov 2021
Risks to the Process issues not carried out

Viamed Ltd ISO13485:2016 7.5.6 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes including: a) defined criteria for

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
issues not carried out

Further Action Required on Issue
0

review and approval of the processes;
b) equipment qualification and qualification of personnel;
c) use of specific methods, procedures and acceptance criteria;
d) as appropriate, statistical techniques with rationale for sample sizes
e) requirements for records (see 4.2.5);
f) revalidation, including criteria for revalidation;
g) approval of changes to the processes.
The organization shall document procedures for the validation of the application of computer software
used in production and service provision. Such software applications shall be validated prior to initial
use and, as appropriate, after changes to such software or its application. The specific approach and
activities associated with software validation and revalidation shall be proportionate to the risk 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).

Process #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.
Updated On : 02 Nov 2021
Risks to the Process issues not carried out

VST Ltd ISO9001:2015 7.1.3 Infrastructure
The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.
NOTE Infrastructure can include:
a) buildings and associated utilities;
b) equipment, including hardware and software;
c) transportation resources;
d) information and communication technology.

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
issues not carried out
Further Action Required on Issue
0

Process #7879 Software Validation Scheduled

Viamed Ltd

Does Update Affect?

Notes On Risk / Benefits statement if required

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.
Updated On : 02 Nov 2021
Training Method Required
Hands on Learning from experienced staff

ISO13485:2016
7.5.6 Validation of processes for production and service provision
The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.
Validation shall demonstrate the ability of these processes to achieve planned results consistently.
The organization shall document procedures for validation of processes including:
a) defined criteria for review and approval of the processes;
b) equipment qualification and qualification of personnel;
c) use of specific methods, procedures and acceptance criteria;
d) as appropriate,

No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

Tasks and Audit Rolling Issues Key to ISO requirements.
risk of losing standards

Further Action Required on Issue
0

statistical techniques with rationale for sample sizes
e) requirements for records (see 4.2.5);
f) revalidation, including criteria for revalidation;
g) approval of changes to the processes.
The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk 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).

Process #7896 Tree In Car Park
To Maintain the Tree in the Car Park
Updated On : 13 Nov 2021
Risks to the Process
the tree may become unsafe

Viamed Ltd
ISO13485:2016
6.3 Infrastructure
The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product.
Infrastructure includes, as appropriate:
a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).
The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As

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
the tree may become unsafe

Further Action Required on Issue
0

appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained

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Process #7897 Daily O2 Sensors Returns
To check the daily returns for any that are oxygen sensors only, so they can be fast tracked through the system
Updated On : 02 Nov 2021
Measurable Objective
the Daily O2 Sensors Returns list

Viamed Ltd
ISO13485:2016
7.5.10 Customer property
The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under the organization's control or being used by the organization. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.5).

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
worst case scenario is sensor returns goes through the system normally
Further Action Required on Issue
0

Process #7923 Review Of

Does Update

Notes On Risk / Benefits statement if required

Credits Received From Suppliers
To Review and tidy up any outstanding RMAs that have been resolved by Supplier credit notes
Updated On : 02 Nov 2021
Measurable Objective
Task History and issues

Viamed Ltd
ISO13485:2016
7.4.2 Purchasing information
Purchasing information shall describe or reference the product to be purchased, including as appropriate:
a) product specifications;
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

Affect?
No
Risk Freqency due to Update
1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

credits missed or not received

Further Action Required on Issue
0

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).

Process #7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications
Updated On : 02 Nov 2021
Risks to the Process
task not carried out

VST Ltd ISO9001:2015 4.2 Understanding the needs and expectations of interested parties
Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:
a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.
The organization shall monitor and review information about these interested parties and

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
task not carried out
Further Action Required on Issue
0

their
relevant requirements.

Process #7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications
Updated On : 02 Nov 2021
Risks to the Process
task not carried out

VST Ltd ISO9001:2015
5.1.2 Customer focus
5.1.2 Customer focus
Top management shall demonstrate leadership and commitment with respect to customer focus by
ensuring that:
a) customer and applicable statutory and regulatory requirements are determined, 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.

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
task not carried out
Further Action Required on Issue
0

Process #7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications

VST Ltd ISO9001:2015
6.2.1
The organization shall establish quality

Does Update Affect?
No
Risk Freqency due to Update

Notes On Risk / Benefits statement if required

Updated On : 02 Nov 2021
Risks to the Process
task not carried out

objectives at relevant functions, levels and processes
needed for the quality management system.
The quality objectives shall:
a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;
g) be updated as appropriate.
The organization shall maintain documented information on the quality objectives

1.Improbable
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

task not carried out

Further Action Required on Issue
0

Process #7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications
Updated On : 02 Nov 2021
Risks to the Process
task not carried out

VST Ltd ISO9001:2015
7.5.1 General
7.5.1 General
The organization's quality management system shall include:
a) documented information required by this International Standard;
b) documented information determined

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
task not carried out

Further Action Required on Issue
0

by the organization as being necessary for the effectiveness of the quality management system.
NOTE The extent of documented information for a quality management system can differ from one organization to another due to:
- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

Process #7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications
Updated On : 02 Nov 2021
Risks to the Process
task not carried out

VST Ltd ISO9001:2015
8.2.1 Customer communication
Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;

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
task not carried out

Further Action Required on Issue
0

d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

Process #7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications
Updated On : 02 Nov 2021
Risks to the Process
task not carried out

VST Ltd ISO9001:2015 8.2.3 Review of the requirements for products and services

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
task not carried out
Further Action Required on Issue
0

Process #7953
Vandagraph Delivery Notifications
To Send Vandagraph Delivery notifications
Updated On : 02 Nov 2021
Risks to the Process
task not carried out

VST Ltd ISO9001:2015 8.2.3.1
The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:
a) requirements specified by the customer,

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
task not carried out
Further Action Required on Issue
0

including the
requirements for delivery
and postdelivery
activities;
b) requirements not
stated by the customer,
but necessary for the
specified or intended
use, when
known;
c) requirements specified
by the organization;
d) statutory and
regulatory requirements
applicable to the
products and services;
e) contract or order
requirements differing
from those previously
expressed.
The organization shall
ensure that contract or
order requirements
differing from those
previously
defined are resolved.
The customers
requirements shall be
confirmed by the
organization before
acceptance, when the
customer does not
provide a documented
statement of their
requirements.
NOTE In some
situations, such as
internet sales, a formal
review is impractical for

each order. Instead, the review can cover relevant product information, such as catalogues.

Process #7961 R D Room - Tidy, Empty Bins, Remove Cups. Caution Around Oxygen Supply
To Clean Tidy the research and development rooms
Updated On : 02 Nov 2021
Scope
To Clean Tidy the research and development rooms

Viamed Ltd
ISO13485:2016
6.3 Infrastructure
The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product.
Infrastructure includes, as appropriate:
a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).
The organization shall document requirements for the maintenance activities, including the interval
of performing the maintenance activities, when such maintenance

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
staff absent so job is not carried out
job not carried out well

Further Action Required on Issue
0

activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained

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Sign Off Report Derek Lamb 23 Nov 2021