



Process Updates Effectiveness Review 02 Aug 2023

Derek Lamb

Process Details	Relevant Standard	Does update Affect/Risk Profile	Notes
<p>Process # Process 80308030</p> <p>Purchase Order Invoice Review</p> <p>Confirm the Price on our purchase order matches the price charged by the supplier Updated On : 23 Jun 2023</p> <p>Scope</p> <p>Confirm the Price on our purchase order matches the price charged by the supplier</p>	<p>Viamed Ltd ISO13485:2016</p> <p>7.4.1 Purchasing process</p> <p>The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.</p> <p>The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:</p> <p>a) based on the supplier's ability to provide product that meets the organization's requirements;</p> <p>b) based on the performance of the supplier;</p> <p>c) based on the effect of the purchased product on the quality of the medical device;</p> <p>d) proportionate to the risk associated with the medical device.</p> <p>The organization shall plan the</p>	<p>Does Update Affect?</p> <p>No</p> <p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>

monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).

Process #	Does Update Affect?	Notes On Risk / Benefits statement if required
 Process <u>80308030</u> Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier Updated On : 23 Jun 2023 Scope	<p>Viamed Ltd ISO13485:2016</p> <p>7.4.2</p> <p>Purchasing information</p> <p>Purchasing information shall describe or reference the product to be purchased, including as appropriate:</p> <ul style="list-style-type: none">a) product specifications;b) requirements for product acceptance, procedures, <p><input type="checkbox"/> No</p> <p>Risk Frequency due to Update</p> <p><input type="checkbox"/> 2.Remote</p> <p>Risk Likely Due to Update</p> <p><input type="checkbox"/> 1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Further Action Required on Issue</p> <input type="text"/>

Confirm the processes and
Price on our equipment;
purchase order matches the
order for qualification
price charged by the supplier
the supplier personnel;
management system
requirements.

The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier.

Purchasing information shall include, as applicable, a written

agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).

Process #

 [Process](#)

[80308030](#)

Purchase

Order

Invoice

Review

Confirm the

Price on our

purchase

order

matches the

price

Viamed Ltd

ISO13485:2016

7.4.3

Verification of

purchased

product

The

organization

shall establish

and implement

the inspection

or other

activities

Does Update

Affect?

Risk Frequency
due to Update

Risk Likly Due
to Update

Action
Required:

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

charged by necessary for
 the supplier ensuring
 Updated On that purchased
 : 23 Jun product meets
 2023 specified
 Scope purchasing
 Confirm the requirements.
 Price on our The extent of
 purchase verification
 order activities
 matches the shall be based
 price on the supplier
 charged by evaluation
 the supplier results and
 proportionate to
 the risks
 associated with
 the
 purchased
 product.
 When the
 organization
 becomes
 aware of any
 changes to the
 purchased
 product, the
 organization
 shall
 determine
 whether these
 changes affect
 the product
 realization
 process or the
 medical device.
 When the
 organization or
 its customer
 intends to
 perform
 verification at
 the supplier's
 premises,
 the
 organization
 shall state the
 intended
 verification
 activities and
 method of
 product release
 in the
 purchasing
 information.
 Records of the
 verification
 shall be
 maintained
 (see 4.2.5).

Process #	Does Update Affect?	Notes On Risk / Benefits statement if required
Process <u>80308030</u> Purchase Order Invoice Review Confirm the Price on our	VST Ltd ISO9001:2015 8.4.3 Information for external providers The organization shall ensure	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible

purchase the adequacy Action
 order of requirements Required:
 matches the prior to their No Action
 price communication Required
 charged by to the
 the supplier external
 Updated On provider.
 : 23 Jun The
 2023 organization
 Scope shall
 Confirm the communicate
 Price on our to external
 purchase providers its
 order requirements
 matches the for:
 price a) the
 charged by processes,
 the supplier 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
 validation
 activities that
 the
 organization, or
 its customer,
 intends to
 perform at the
 external
 providers♦
 premises.

Further Action Required on Issue

Process #	Does Update Affect?	Notes On Risk / Benefits statement if required
 Process 80308030 Purchase Order Invoice Review Confirm the Price on our purchase	VST Ltd ISO9001:2015 9.1.3 Analysis and evaluation The organization shall analyse and evaluate appropriate <input style="width: 100px; height: 20px; margin-bottom: 5px;" type="button" value="No"/> Risk Frequency due to Update <input style="width: 100px; height: 20px; margin-bottom: 5px;" type="button" value="2.Remote"/> Risk Likly Due to Update <input style="width: 100px; height: 20px; margin-bottom: 5px;" type="button" value="1.Negligible"/>	

order	data and information	Action Required:	Further Action Required on Issue
matches the price charged by the supplier	arising from monitoring and	No Action Required	
Updated On : 23 Jun 2023	measurement.		
Scope	The results of analysis shall be used to		
Confirm the	evaluate:		
Price on our purchase order	a) conformity of products and services;		
matches the price charged by the supplier	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.		

Sign Off Report Derek Lamb 02 Aug 2023