








Process Updates Effectiveness Review 02 Aug 2023Derek Lamb

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

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 8030 Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier Updated On : 23 Jun 2023 Scope	Viamed Ltd ISO13485:2016 7.4.2 Purchasing information shall describe or reference the product to be purchased, including as appropriate: a) product specifications; b) requirements for product acceptance, procedures,	<div> <div> <div>No</div> <div>▼</div> </div> <div> <div>Risk Frequency due to Update</div> <div>2.Remote</div> <div>▼</div> </div> <div> <div>Risk Likly Due to Update</div> <div>1.Negligible</div> <div>▼</div> </div> <div> <div>Action Required:</div> <div>No Action Required</div> </div> </div> <div> <div>Further Action Required on Issue</div> <div></div> </div>

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


Process #		Does Update Affect?	Notes On Risk / Benefits statement if required
 Process 8030	Viamed Ltd ISO13485:2016 7.4.3 Verification of purchased product	No 	<div></div> 
Purchase Order Invoice Review	The organization shall establish and implement the inspection or other activities	Risk Frequency due to Update 2.Remote 	
Confirm the Price on our purchase order matches the price		Risk Likly Due to Update 1.Negligible 	
		Action Required: No Action Required	

Further Action Required on Issue

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

Process #		Does Update Affect?	Notes On Risk / Benefits statement if required
 Process 80308030	VST Ltd ISO9001:2015 8.4.3 Information for external providers The organization shall ensure	No  Risk Frequency due to Update 2.Remote  Risk Likly Due to Update 1.Negligible 	<div></div> 

purchase order matches the price charged by the supplier	the adequacy of requirements prior to their communication to the external provider.	Action Required: No Action Required	Further Action Required on Issue
Updated On : 23 Jun 2023	The organization shall communicate to external providers its requirements for:		
Scope	a) the processes, products and services to be provided;		
Confirm the Price on our purchase order matches the price charged by the supplier	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.		

Process #	Does Update Affect?	Notes On Risk / Benefits statement if required
 Process 8030 8030 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	<div> <div>No</div> <div>Risk Frequency due to Update</div> <div>2.Remote</div> <div>Risk Likly Due to Update</div> <div>1.Negligible</div> </div>

order matches the price charged by the supplier	Updated On : 23 Jun 2023	Scope	Confirm the Price on our purchase order matches the price charged by the supplier	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.	Action Required: No Action Required	Further Action Required on Issue
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