
	Internal Audit Report	QF10-01: Rev 1.0 Effective date: 23/12/2022
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1- Internal Audit information:

Activities Audited	Sales and Purchasing ISO 13485:2016: 7.1, 7.2, 7.4.1, 7.4.2, 7.4.3 CMDR 14, CMDR 9(2), 21-23, 52-56, 66-68, CMDR 9(2), CMDR 52-53, CMDR 54, 66-68, TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d)(ii), TG(MD)R Sch1 P1 2, TG(MD)R Sch1 P1 2, Sch3 1.4(5)(e) 21 CFR 820.20, 820.50, (a), (b), 820.65, 820.80(b), 820.100, 820.160 MDSAP Chapter 7, Tasks 1 – 12.
Audit Date(s)	2024-06-13
Audit Date scheduled (as per Audit schedule)	June 10, 11, 13, 2024
Internal Auditor(s)	Gordon Forest, VL Solutions Inc. 
Employees audited	Étienne Lefort, Fatima Chaouki, Tabitha Jaramillo, Ghasia Chaib, Albert Mouawad
Department Manager	Étienne Lefort

2- Audit Summary:

A procedure for contract review has been established under QP02, Rev. 4.0 whose objective is to establish procedures and responsibilities for comparing customer's requirements to Thorasys' ability to provide and deliver the requested products and services.

The following design history records are kept for a minimum of 10 years.

- Quotation (recorded in Odoo)
- Customer Purchase Order (scanned version) - identified records (scanned copies) are uploaded to the ERP system (Odoo) under the corresponding order/lot/serial number.
- Commercial Invoice (where applicable) (scanned version)
- Packing Slip (scanned** or Odoo record)
- QF02-01 Sales Order Confirmation
- QF06-02 Order Preparation Sheet

QF02-01 and QF06-02 are created, signed, and stored in the ERP systems. The ERP system is subject to 21 CFR Part 11.

Customer Orders

SOP-2, Ver. 2.0 Sales and Purchasing

No on-line sales are made at Thorasys.

Onboarding: Web platform called myThorasys. Typically, a 1-hour session is arranged with the customer, to make sure they have a good comprehension of the product. Requests for information are managed with tickets.

Sales team receives a request for Thorasys product in writing or verbally and prepares a quotation on the ERP system (QI-11 Creating quotations and Sales Orders in Odoo).

Customer	Sonmedica vas, Jorge Vazquez Carrer del Congost, 28 08024 Barcelona Spain – ESB62011093	Order Date	24/05/2024 10:18:09
Dashboard Country Groups	Europe (Sales Dashboard)	Pricelist	EUR Retailers (EUR)
Invoice Address	Sonmedica vas, Jorge Vazquez	Payment Terms	Net 30 Days - EU (Intra-EC)
Delivery Address	Sonmedica vas, Jorge Vazquez	Has Products	Commercial Products
Quotation Template		Type of Sales Order	Sale

Product	Description	Versi...	Ordered Quanti...	Delivered	Invoiced	Unit Price	Tax...	Disc.%	Subtotal
[101336] tremoFlo C-100 Devic...	[101336] tremoFlo C-100 Device ClearFlo compatible	6	1.00	0.00	0.00	4,690.00		0.00	4,690.00 €
[101923] tremoFlo C-100 Supp...	[101923] tremoFlo C-100 Support Arm	2	1.00	0.00	0.00	323.00		0.00	323.00 €

Please use customers UPS STANDARD account 61R1R2

Serial No for support arm: 145596
The SN of the C-100 will be updated line by line in the sales order.

When the line items are all updated, the order is ready to ship.

SO2600 – being sent to a distributor in the US. The line items are added, and the sales order is reviewed by a second person (electronic signatures).

☆ MON/OUT/04517

Delivery Address	Morgan Scientific, Inc, Heather J. Blais	Scheduled Date	12/04/2024 13:44:55
Country	United States	Effective Date	12/04/2024 12:28:18
Source Location	MON/Stock	Source Document	SO2600
		Type of Sales Order	Sale

Destination Location	Product	Description	Demand	Done	Unit of Measure
Partner Locations/Customers	[101059] tremoFlo C-100 Calibrated Reference Loa...	tremoFlo C-100 Calibrated Reference Load 15 cm H2O.s/L	1.00	1.00	Units
Partner Locations/Customers	[101524] tremoFlo C-100 Airwave Oscillometry Syst...	tremoFlo C-100 Airwave Oscillometry System & Accessories - US Edition	1.00	1.00	Units
Partner Locations/Customers	[102061-12] tremoFlo software GDT Healthcare lice...	tremoFlo software GDT Healthcare license	1.00	1.00	Units

☆ MON/OUT/04517

Delivery Address Morgan Scientific, Inc, Heather J. Blais
Country United States
Source Location MON/Stock

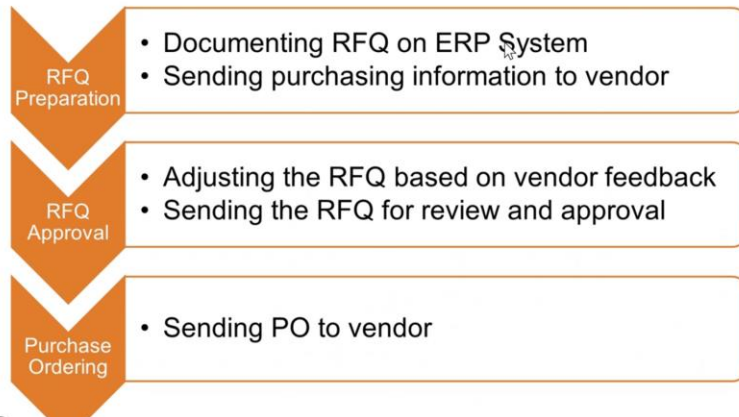
Scheduled Date 12/04/2024 13:44:55
Effective Date 12/04/2024 12:28:18
Source Document S02600
Type of Sales Order Sale

Detailed Operations	Operations	Additional Info	Note					
Product	From	Destination Package	Lot/Serial Number	Lot/Serial Number Name	Reserved	Done	Ur	
101059] tremoflo C-100 Calibrated Reference Load 15 cm H2O.s/L	MON/Sto...		142871		0.00	1.00	Ur	
101524] tremoflo C-100 Airwave Oscillometry System & Accessories...	MON/Sto...		143151		0.00	1.00	Ur	
102061-12] tremoflo software GDT Healthcare license (12 months)	MON/Sto...		145857		0.00	1.00	Ur	

Purchasing

SOP-2 Purchasing requirements: Ver. 2.0 7.2 Purchasing

The process to purchase goods or services is described in the flowchart below:



Purchasing process:

Requesting a quotation: Complete an RFQ in the ERP system. Part number, description and revision must be on the RFQ.

The Purchaser must attach the specification documentation to the RFQ (such as, but not limited to, drawings or specifications), or send the specification documentation directly to vendor, to communicate the purchasing information to the vendor. This is optional for purchases made directly from the vendor's website (online orders).

If orders are placed with suppliers who are not on the ASL, they have to be indicated as R&D suppliers on the ERP system (the selection is made automatically on the ERP system).

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PO are reviewed and approved depending on what is being purchased and the dollar amount being spent.

	CEO or President Top Management Representative	Logistics, Production, and Operations Top Management Representative
Parts, Raw Materials, Components, and other goods for Production	For purchases > 10 000 CAD	For purchases ≤ 10 000 CAD
All other purchases	All purchases	N/A

Purchased goods are received and verified as per SOP-29 Ver. 1.0, Incoming Inspection, as required. This procedure was released in Dec. 2023, and not all the receiving inspections are compliant with this new procedure. Sampling is done according to ISO 2859-1. The inspection is recorded in Odoo and if accepted it is identified as goods accepted from approved vendors. If it is not accepted it is controlled under SOP-8 Nonconforming Product Control.

If no sample size is defined, the product goes through 100% inspection.

Inspection protocols have been developed for the majority of parts. There are exceptions (off-the-shelf) purchases are handled by another procedure.

Documenting Incoming Inspection Results

The Inspector documents the results of all incoming inspection activities on the ERP system.

Include the following information when documenting incoming inspection results where applicable:

- 1 The equipment number of any equipment used to perform the inspection,
2. The value of any measurement results taken during the inspection.

Additionally, attach all accompanying documentation to the incoming inspection report on ERP system.

The inspector affixes the Approved Materials Label if the Quality Team approves the lot of incoming goods. The fields of the Approved Material labels are populated automatically by the ERP system.

An example of the Acceptance label is provided for PO 00866 Vendor: Graphisme, P/N 10116.



Products		Other Information											
Product	Description	Versi...	Quantity	Lot/Serial	Received	Remaining Qu...	Billed	UoM	Unit Price	Taxes		Subtotal	
[101999] tf C2 S...	[101999] tf C2 Support Arm Printed Sleeve	1	100.00	143804	100.00	0.00	100.00	Units	21.70	GST + QST for ...		2,170.00 C\$	
Please print the [101999] tf C2 Support Arm Sleeve without [CLICK UP].													

This is a graphical design sleeve which goes onto the box for the C2 forearm. Quantity ordered: 100, received: 100 units. Lot No 143804. 17/08/2023.

Receiving: unique identification MON/IN/01095. Received the ordered quantity of 100 units.

Quality check: Quantity received: checked


CofC: Certificate of compliance:

Compare the material with the specification using the DMR (exactness of content, reproduction, print quality, legibility).

1		2		3		4	
NOTES:				REVISIONS			
1. PAPER THICKNES: 12 PT				REV	ZONE	DESCRIPTION	TCO#
2. PAPER FINISH: GLOSSY							
3. FINISH: CUT TO FINAL SIZE, GROOVE, DOUBLE-SIDED ADHESIVE TAPE. MATRIX. READY TO STICK				1	ALL	INITIAL RELEASE	TCO-103039

As the reception of the sleeves from Graphisme was done before the full implementation of the SOP-29, the absence of the CofC would not have been flagged. If this were to occur at reception in 2024, the absence of a CofC would be documented as a non-conformity and the material handled through the process for control of non-conforming product.

I checked the ASL for VL Solutions Inc, Registrar Inc. and Bird Healthcare (Australian sponsor). These vendors have not yet migrated to the new system. They are identified as approved vendors in the old system.

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Thorasys is currently in the process of transferring all the vendors from the old system to the new system (Qualio).

Supplier qualification and requalification assessment (form QF05-07 Rev. 2.0 is completed for: VL Solution Inc., Approved: 25/09/2023.

Registrar: (Agreement 20/12/2019) responsible for Establishment registration and device listing, a confirmation was received for the listing of Impedance measuring device utilizing oscillation techniques (product code: PNV),

Bird Healthcare: there is a myriad of agreements and certification to fulfill the requirements of a sponsor. Because this vendor has been used for several years, it has not gone through the same qualification process.

Supplier Selection and Evaluations

Qualification of new vendors with the Qualio System.

Enviroplass vendor qualification: qualified new with the new system. Level 2.

Services provided: Product evaluation – product compliance verification to standards such as REACH and RoHS., environmental compliance auditing, regulatory monitoring, implementation of environment management systems EMS ISO 14001.

Risk-based Classification levels 1 to 5: Class 5 is the highest risk level where level 1 is the lowest (off-the-shelf providers). Approved (on Qualio Properties menu) 01/03/2024.

Alerkan Healthcare level 5 supplier: PFT Filters and Nose Clips. Vendor is ISO 13485: 2016 certified (certificate M 11378), expiration 18-01-2026.

Supplier evaluation: example Alerkan is due for evaluation in 9 months. No vendors have yet been evaluated using the Qualio system. Criteria for evaluation: Form VEVAL (prefix given in Qualio, Ver. 4.0. Evaluation id done based on Number of NCs, (provide NC document numbers), No of SCARs, which SCARs, Changes made without notification, Quality of received goods/services, Timelines of delivery, Communication & responsiveness, Overall satisfaction, total points on 35.

Evaluation of whether the evaluation has improved or declined, If a SCAR required to address the decline in performance, Are any other actions required to address the decline in performance, was the re-evaluation performed by the due date (risk assessment required associated with evaluations beyond the due date).

Distributors are evaluated based on Customer and technical support, reporting problems to Thorasys, Communication with authorities, Overall satisfaction. (Excellent – 5 pts, Good – 4 points, Acceptable – 3 points, Poor – 2 points, very poor – 1 point). A total of 35 points is a perfect score. Different evaluations are done for other subcontractor Evaluations.

Note: Thorasys does not conduct any online sales.

3- Non-Conformities:

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- **NC#ID:** NCxx
- **Category:** Minor ☐ Medium ☐ Major ☐
- **NC Description** (including reference and evidence):

No non-conformities were detected for this process.

4- Opportunities For Improvement:

No opportunities for improvement were detected in this process.

Documented /Approved by	Name:	Signature:	Date:
Department Manager	Etienne Lefort		25-Jul-2024 EDT
Quality Assurance	Etienne Lefort Signer ID: HEBIXRYNS... 25 Jul 2024, 13:33:54, EDT Signing Reason: I approved this document	Tabitha Jaramillo	25-Jul-2024 EDT
	Tabitha Jaramillo Signer ID: INFXXQWVX... 25 Jul 2024, 13:33:23, EDT Signing Reason: I approved this document		

Signature Certificate



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Author: Fatima Chaouki Creation Date: 10 Jul 2024, 10:16:07, EDT Completion Date: 25 Jul 2024, 13:33:23, EDT

Document Details:



Name: Internal Audit Report Design and Development Process - June 2024

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Document Total Pages: 11



Name: Internal Audit Report Marketing Authorization - June 2024

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Document Total Pages: 7



Name: Internal Audit Report Measurement Analysis and Improvement - June 2024

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Document Total Pages: 24



Name: Internal Audit Report Medical Device Adverse Events and Advisory Notice Reporting Process - June 2024

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Document Ref: a991dc4e3d45975521036c90e3cb066ce56e374b6512a415b0681e0196ea e39f

Document Total Pages: 3



Name: Internal Audit Report Production and Service Controls Process - June 2024

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Document Total Pages: 10



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YVI Solutions



Name: Internal audit summary report - 2024 - Corrected

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Document Total Pages: 2

Document Signed By:

Name: Tabitha Jaramillo

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Date: 25 Jul 2024, 13:33:23, EDT

Consent: eSignature Consent Accepted

Security Level: Email, Account Login Password Authentication

Tabitha Jaramillo

Tabitha Jaramillo
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Signing Reason: I approved this document

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Consent: eSignature Consent Accepted

Security Level: Email, Account Login Password Authentication

Etienne Lefort

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Consent: eSignature Consent Accepted

Security Level: Email, Account Login Password Authentication

Ghania Chaib

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Lucas Posada
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11 Jul 2024, 15:51:33, EDT
Signing Reason: I approved this document

IP: 69.70.57.54
Location: MONTREAL, QC (CA)
Date: 11 Jul 2024, 15:51:33, EDT
Consent: eSignature Consent Accepted
Security Level: Email, Account Login Password Authentication

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Signed Document(s)	Link emailed to lucas.posada@thorasys.com
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