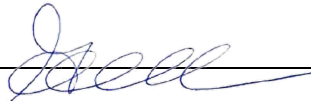


THORASYS™	Internal Audit Report	QF10-01: Rev 1.0 Effective date: 23/12/2022
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1- Internal Audit information:

Activities Audited	Production and Service Controls Process ISO 13485:2016: 6.2, 6.4, 6.4.2, 7.1, 7.2.1, 7.5.1, 7.5.2, 7.5.3, 7.5.6, 7.5.8, 7.5.9, 1, 7.5.11, 7.6, 8.1, 8.2.5, 8.2.6, 8.3, 8.3.4, 8.4 CMDR 14, CMDR 9(2), 21-23, 52-56, 66-68, CMDR 9(2), CMDR 52-53, CMDR 54, 66-68, TG(MD)R Sch 1 P1 2, Sch3 P1 Cl1.4(4), Sch3 P1 Cl1.4(5)(d)&(e), TG(MD)R Sch3 P1 Cl1.4(5)(d), TG(MD)R Sch1 P2 7.2, 8, TG(MD)R Sch3 P1 1.4(5)(e), TG(MD)R, Sch1 EP13, Sch3 P1 1.4(5) (c),(d),(e) & 1.9, TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d), TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(b), TG(MD)R Sch1 P1 4&5, TG(MD)R Sch1 P1 2&5. 21 CFR 801, 820.30(b), 820.20(a), 820.25, 820.30(h), 820.65, 820.70(a), 830, 21 CFR 820.70(c), 820.70(d), 820.70(e), 820.70(h), 820.70(i), 820.70(g), 820.70(f), 820.72, 820.75, 820.86, 820.90(a), (b), 820.100(a), 820.120(e), 820.130, 820.140, 820.150, 820.1609(a), 820.181, 820.184, 820.200, 820.250(a), (b) MDSAP Chapter 6, Tasks 1-29
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, G. Chaib
Department Manager	Ghania Chaib

2- Audit Summary:

Software validation: (see software validation in measurement, Analysis and Improvement Report)

Odoo is used to keep track of the device, and the components used to build the device.

During the audit, I verified the assembly, sub-assembly and final assembly of:

Finished product: 101336 TremoFlo C-100 Device ClearFlo compatible, SN: 146111 – destined for the US market.

[Products / \[101336\] tremoFlo C-100 Device ClearFlo compatible](#)

[/ Lots/Serial Numbers / 138014 / Traceability Report / Traceability Report](#)

[/ WH/MO/09926 / Traceability Report / WH/MO/09926](#)

The system breaks down all the subassemblies used is the assembly of the kit.

Example screen shot:

Lots/Serial Numbers / 138014 OLD / Traceability Report

PRINT

▼ WH/MO/04823	[101336] tremoFlo C-100 Device ClearFlo compatible	12/05/2022 11:23:32	138014 OLD	Production	Stock
WH/MO/04823	[101584] Thread-Forming Screw for Plastic, 18-8 Stainless Steel, 0-42 Thread, 3/16" Length	12/05/2022 11:23:32		Stock	Production
WH/MO/04823	[101293] Thread-Forming Screw for Plastic 18-8 SS, 4-20 Thread, 3/8" Length	12/05/2022 11:23:32		Stock	Production
WH/MO/04823	[101335] tremoFlo C-100 Airwave Oscillometry System Label	12/05/2022 11:23:32		Stock	Production
▶ WH/MO/04823	[100782] tF C-100 HHU BACK SHELL Inj. Mold	12/05/2022 11:23:32	134470	Stock	Production
▶ WH/MO/04823	[100783] tF C-100 HHU_LENS LIGHT PIPE Inj. Mold	12/05/2022 11:23:32	134472	Stock	Production
▶ WH/MO/04823	[100784] tF C-100 HHU_LOOVER REAR PLATE Inj. Mold	12/05/2022 11:23:32	134473	Stock	Production
▶ WH/MO/04823	[100787] tF C-100 HHU_SCREW CAP Inj. Mold	12/05/2022 11:23:32	136888	Stock	Production
▶ WH/MO/04823	[100789] tF C-100 HHU_FRONT CAP Inj. Mold	12/05/2022 11:23:32	134471	Stock	Production
▶ WH/MO/04823	[100791] tF C-100 HHU_NAME PLATE Inj. Mold	12/05/2022 11:23:32	134463	Stock	Production

The significance of OLD is due to the fact that production discovered that the traceability records were not being recorded, and a new record was created that did product the traceability records. Since the tow files could not exist under the same name, the designation OLD was added to distinguish the record that produced all the traceability records.

THORASYS

Inspection Protocol
and Report

Document No.: INP-101336, INP-101490,
INP-101574, INP-101596, INP-102100
Revision No.: 17.0

Check box for inspected part	Part Number & Name	Revision	Serial Number	
<input checked="" type="checkbox"/>	101336 tremoFlo C-100 Unit - ClearFlo PFT filter	4	138014	
<input type="checkbox"/>	101490 tremoFlo C-100 Unit - SRG PFT filter			
<input type="checkbox"/>	101574 tremoFlo P-100 Unit - Preclinical Configuration			
<input type="checkbox"/>	102100 tremoFlo C-100 Unit - Ganshorn Compatible			
<input type="checkbox"/>	101596 tF C-100 Unit-LEMON PFT filter compatible			
RIBBON CABLES				
ITEM #	CHECK	EXPECTED	PASS	FAIL
		The smaller ribbon cable PN100153 has glue applied over both extremities of cable and connectors. The larger ribbon cable PN100152 has glue		

ITEM #	CHECK	EXPECTED	PASS
1	Verify that all ribbon cables are fix with hot melt glue	The smaller ribbon cable PN100153 has glue applied over both extremities of cable and connectors. The larger ribbon cables PN100152 have glue applied over both extremities of cable and connectors on the front side AND back side of the cable.	<input checked="" type="checkbox"/>
PFT CHECKS			
ITEM #	CHECK	EXPECTED/ACTION	PASS
2	Pneumotach Mesh	Verify that the pneumotach mesh is installed in the filter interface subassembly	<input checked="" type="checkbox"/>
3	PFT Interface Check	Verify that the Filter Assy is tightly screwed in AND is compatible with the proper filters	<input checked="" type="checkbox"/>
CALIBRATION CHECKS			
ITEM #	CHECK	EXPECTED/ACTION	PASS
4	Calibration record	Ensure the calibration of the channels and the dynamic calibrations were performed and that the calibration record (form FRM-102162) was filled. Confirm every Pass/Fail check is a Pass.	<input checked="" type="checkbox"/>
5	EDS information using the latest SDM editor program	Ensure the EDS information is accurate and matches the device calibration record (form FRM-102162)	<input checked="" type="checkbox"/>

THORASYS™	Internal Audit Report	QF10-01: Rev 1.0 Effective date: 23/12/2022
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6	Turn on the tremoFlo device	Handheld light & cu power button flash	NA
7	Open tremoFlo software in Support Mode. On the Welcome screen, press the X icon and go to the TREMOFLO tab, select Devices and QA Wizard	Software starts, Welcome screen displayed, software connects to the device, motor autocalibrates, channel zeroing and finally QA wizard starts.	NA

The equipment used for testing is identified in attachment:

Purpose: Channel Calibration Record for the tF C100			
Calibrated By:	Ghania Chaib	Calibration Instruction	WI-102163 Revision: 8
Calibration date:	5/9/2022	Device Serial Number:	138014
Device Model Number:	101336	Revision:	4
Test Conditions for Calibration			
Temperature & Humidity Meter Asset #:	OS0147		
Room Temperature [°C]:	23	Relative Humidity [%]:	23
ometric Pressure [kPa]:	103.2		
Standards Used to Establish Traceability			
Instrument Type	Model	Asset # or serial #	
Differential Pressure Manometer	TSI, DPCAL-5815	OS0143	
Flowmeter	TSI, Model 40211	OS0140	R.Nom [cm H ₂ O.s/L]
R2 reference load	100986	115904	2.12
R15 reference load	101059	108504	15.36

I verified the calibration record for OS0143 Differential Pressure Monometer MODEL TSI, PDCAL-5815. Calibration date: 27-9-2022. Received 19-09-2022 and certificate issued SN T58151407001. As found: In tolerance. The standards used to calibrate the equipment are traceable to NIST standards.

This equipment is calibrated annually, so a calibration was done on October 9, 2023. As found: in tolerance. There is proof that the calibration certificate was verified through the Calibration History Form QF07-01, Rev. 2.0 for SN T58151407001. The form indicates that the calibration was (in Cal, Out of Cal, Repair) – in this case the result was In Cal. The document is signed and dated.

QP07 Equipment Calibration Process, Rev. 3.0. Revision 3.0

3.0	Per CAP-100105 and CAP-100117: clarify responsibilities for calibration activities; require opening NC report when calibration certificate indicates that equipment was found to be out of calibration and perform a risk assessment in the NC report; require that a calibration interval has to be performed for all equipment in calibration system and provide rationale for interval. Moved Calibration index to Odoo Maintenance Module	06/03/2023
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Wrist strap checker: OS0004-A: Model No. DB62-11M, Request date: 30-05-2025. Last calibration was done on 30-05-2024 by Transcat Canada. As Found/Left: Pass.

Verification of Calibration Label:

	<h1>Internal Audit Report</h1>	<p>QF10-01: Rev 1.0 Effective date: 23/12/2022</p>
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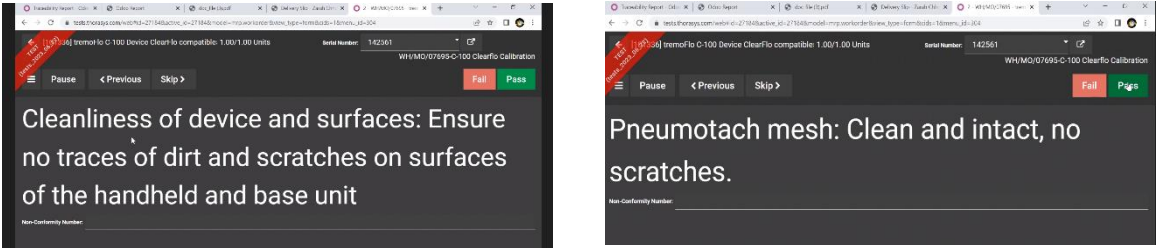
Environmental Controls: when contact between personnel and the product or the manufacturing environment could adversely affect the quality of the product, the requirements for health, cleanliness and clothing of personnel as well as environmental controls related to manufacturing are described and if applicable, instructions related to its procedure.

All employees who are required to work temporarily under special environmental conditions are trained or supervised by a trained person.

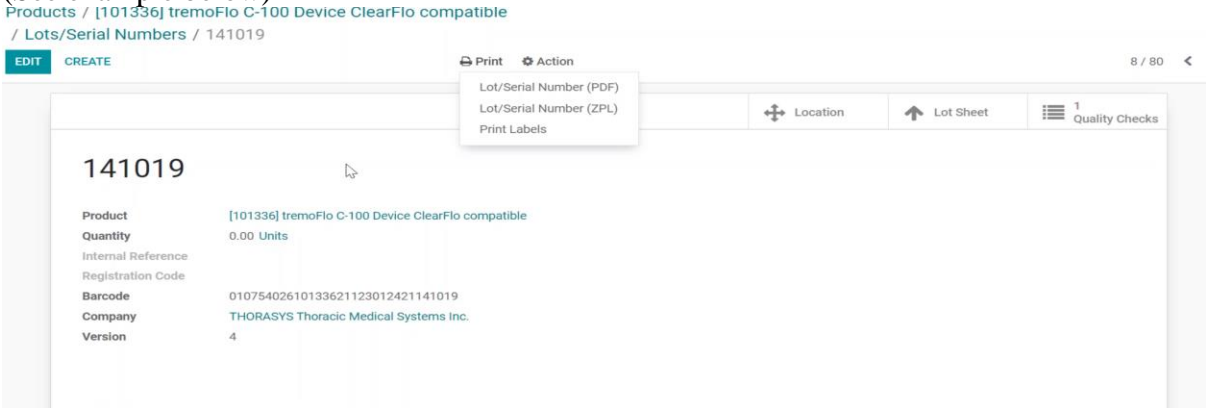
ESD control is critical in manufacturing activities and product quality and is described in quality instruction QI06-01, Rev. 4.0 ESD Protection Instruction. This procedure applies to the receiving, handling, storage and assembly of all parts designated as ESD sensitive used in the production of products sold by THORASYS.

Thorasys has implemented a pest control programme with monthly inspections by Mahieu Mahieu. I viewed the report for 2024-06-12 (contract # C105636) and though there was 1 audlt domestic mouse in an interior trap, there were no findings that would indicate an infestation of parasites or rodents.

Specific requirements related to product cleanliness are controlled during assembly:
 Examples :



WH/MO/06676 Lot sheet (QF06-01, Rev. 10)
 (See example below)



Lot Sheet

Product	Lot/Serial #	Version	INP	Rev	Quantity
[101336] tremoFlo C-100 Device ClearFlo compatible	141239	4	19		1.00 Units
[101584] Thread-Forming Screw for Plastic, 18-8 Stainless Steel, 0-42 Thread, 3/16" Length		1			2.00 Units
[101293] Thread-Forming Screw for Plastic 18-8 SS, 4-20 Thread, 3/8" Length		1			3.00 Units
[101335] tremoFlo C-100 Airwave Oscillometry System Label		9			1.00 Units
[100782] tF C-100 HHU BACK SHELL Inj. Mold	139525	3			1.00 Units
[100783] tF C-100 HHU LENS LIGHT PIPE Inj. Mold	139600	2			1.00 Units
[100784] tF C-100 HHU LOOVER REAR PLATE Inj. Mold	136894	2			1.00 Units
[100787] tF C-100 HHU SCREW CAP Inj. Mold	136888	2			3.00 Units
[100789] tF C-100 HHU FRONT CAP Inj. Mold	136893	2			1.00 Units
[100791] tF C-100 HHU NAME PLATE Inj. Mold	136895	2			1.00 Units
[101397] tF C100 pre-calibration	141069	5			1.00 Units
[101414] tF C100 Alerkan dust cap	139647	1			1.00 Units
[101412] tF C-100 Alerkan PFT Filter Assembly	141188	4			1.00 Units

Quality checks: (see the following screen shots)

Quality Checks

QC#	Title	Description	Result
QC218710	Screw Check AQL 100%	Verify screws are present and properly screwed as specified.	Success
QC218711	Visual Inspection AQL 100%	Ensure custom cable 101106 is securely attached on both the Handheld and CU	Success
QC218712	Programming check AQL 100%	Power the unit. Ensure lights on handheld shine blue steady. Ensure lights on CU shine yellow steady.	Success
QC218713	Functional test AQL 100%	Connect to the tF SW and start a test. Ensure the device is connecting and initializing properly	Success
QC218714	HH Button function test AQL 100%	Run a few measurements. Ensure both handheld buttons are working and that Pressure, Flow and Volume trace are stable.	Success
QC218715	Motor stability/noise test AQL 100%	Start another measurement. Ensure there is no excessive rattling/buzzing/humming noise and that the piston move smoothly	Success
QC218716	CU power button AQL 100%	Ensure Power Button (PN100796) is securely glued to the Control Unit Top Enclosure (PN100793) and that it moves freely (not sticking)	Success

QF06-01 REV. 7.0 - Effective Date: 30/06/2022

QC#	Title	Description	Result
QC218717	Lot ID AQL 100%	Ensure that main assembly has a lot number label on the FOT module PN100318 and on the CU Unit PN100506	Success

Traceability Report x Odoo Report x Odoo Report x Print Labels - 2023 x Odoo Report x 1 - WH/MO/07694 x

tests.thorasy.com/web?id=27180&active_id=27180&model=mrp.workorder&view_type=form&cids=1&menu_id=304

TEST [100792] tF C100 pre-calibration: 1.00/1.00 Units Lot Number: 142560 WH/MO/07694-Pre-Calibration Assembly

Pause < Previous Skip > VALIDATE CONTINUE CONSUMPTION

Component [100792] tF C-100 CCU Enclosure front Inj. Mold Lot Number 139589 Quantity 1.00 / 1.00 Units

TEST [100792] tF C100 pre-calibration: 1.00 / 1.00 Units Lot Number: 142560 WH/MO/07694-Pre-Calibration - Part Inspection and Quality Instructions

Pause < Previous Skip > Fail Pass

Ensure all screws are present and properly screwed as specified in drawings 101397 and 100506.

Non-Conformity Number: _____

02:33:01 Chat People Raise React View More Cam

Traceability Report x Odoo Report x Odoo Report x Print Labels - 2023 x Odoo Report x 3 - WH/MO/07694 x

tests.thorasy.com/web?id=27182&active_id=27182&model=mrp.workorder&view_type=form&cids=1&menu_id=304

TEST [100792] tF C100 pre-calibration: 1.00/1.00 Units Lot Number: 142560 WH/MO/07694-Pre-Calibration - Part Inspection and Quality Instructions

Pause < Previous Skip > Fail Pass

Using torque wrench OS-0044-A, ensure item 5 is torqued to 5 lbs-in as specified in drawing 100506.

Non-Conformity Number: _____


	<h1>Internal Audit Report</h1>	<p>QF10-01: Rev 1.0 Effective date: 23/12/2022</p>
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Shipping:

Product 101366: an EU label for tremoflo C-100 Airwave Oscillometry System:



Label for shipping box: a label for tremoflo C-100 Airwave Oscillometry System and Accessories – US Edition– (101524) UDI identify: scan UDI code and displays all the elements related to the UDI code:

	<h1>Internal Audit Report</h1>	<p>QF10-01: Rev 1.0 Effective date: 23/12/2022</p>
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Competence of personnel:

I have verified that job descriptions are available for the various job functions at Thorasys:

The job descriptions for the following functions were reviewed and found to be compliant for the determination of competencies required for the specific job functions: Director of Production and Logistics (Albert Mouawad), R&D Manager (Lucas Posada), Director of QA & IT and Management Representative (Étienne Lefort), Clinical Science Director (Lennart Lundbald).

Example of Clinical Science Director's job description: QF11-02, Rev. 1.0, Job description revision 1.0 (2019-03-18): Competence required: Good understanding of scientific data analysis and statistics, An outgoing personality with excellent communication skills, Strong organizational skills, Full working proficiency in English, including excellent scientific writing skills, Willingness to travel regularly, A solid understanding of the regulatory framework for medical devices is an asset, and Working proficiency in French and other spoken languages is an asset.

Training: I reviewed the training program throughout the audit and found it to be effectively implemented: Training records reviewed are reported in the Internal Audit Report for MAI as for example Training conducted for QP06, Rev. 6.0 as well as for QP7, Rev. 4.0 (May 8 and June 30, 2024). Training is managed through Qualio.

Control of monitoring and measuring equipment:

THORASYS™	Internal Audit Report	QF10-01: Rev 1.0 Effective date: 23/12/2022
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Torque wrench-2 SN OS0150 Model DSIFI5CHNMC -Eternal calibration – Ulrich Metrology, calibration date 2023-03-13, recalibration date: 2023-09-12.

Master test load R5 – Internal calibration, calibrated on 2022-07-11, recalibration date: 2023-08-01.

Wrist Strap Tester SN OS0004-A, Model B8203, External calibration – Ulrich Metrology, calibration date: 2023-05-29, recalibration date: 2024-05-29.

I have determined that the calibration program is effectively implemented at Thorasys.

3- Non-Conformities:

- **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	<i>Ghania Chaib</i>		25-Jul-2024 EDT
Quality Assurance	Ghania Chaib Signer ID: D01F5GSV9JH... 25 Jul 2024, 09:21:10, EDT	<i>Tabitha Jaramillo</i>	25-Jul-2024 EDT
	Tabitha Jaramillo Signer ID: INFXXQWVX... 25 Jul 2024, 13:33:23, EDT Signing Reason: I approved this document		

Signature Certificate



Envelope Ref:ae760810abfcc5823fe393328b35ea5440733f21

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

Type:

Document Ref: 00d44092572e1fb9fb07cdf5ba25d88e0d6699e1cd1809f8b301e7a7fe7b36b7

Document Total Pages: 11



Name: Internal Audit Report Marketing Authorization - June 2024

Type:

Document Ref: 35eb680dbd1a9232d0e91a198247763e268c61b1c634d9ec53b5fb604075316e

Document Total Pages: 7



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

Type:

Document Ref: e4f0153e6e3c3983e69298f095766af5a9edc0186eb98890e26a801d6182ef54

Document Total Pages: 24



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

Type:

Document Ref: a991dc4e3d45975521036c90e3cb066ce56e374b6512a415b0681e0196ea e39f

Document Total Pages: 3



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

Type:

Document Ref: da29b0d0922bc5d491f9358586b448d4323c44c7e35008e429784ee251eb0262

Document Total Pages: 10



Name: Internal Audit Report Sales and Purchasing Process - June 2024

Type:

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Document Total Pages: 7

YVI Solutions



Name: Internal audit summary report - 2024 - Corrected

Type:

Document Ref: 65a58bb305e79723c1455ccd94b23e43245f0676fa0470540254f32710f5c6d5

Document Total Pages: 2

Document Signed By:

Name: Tabitha Jaramillo

Email: tabitha.jaramillo@thorasys.com

IP: 104.221.20.56

Location: MONTREAL, QC (CA)

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

Consent: eSignature Consent Accepted

Security Level: Email, Account Login Password Authentication

Tabitha Jaramillo

Tabitha Jaramillo
Signer ID: INFXXWQVX...
25 Jul 2024, 13:33:23, EDT
Signing Reason: I approved this document

Name: Etienne Lefort

Email: etienne.lefort@thorasys.com

IP: 70.53.167.187

Location: KIRKLAND, QC (CA)

Date: 25 Jul 2024, 12:16:54, EDT

Consent: eSignature Consent Accepted

Security Level: Email, Account Login Password Authentication

Etienne Lefort

Etienne Lefort
Signer ID: HEBIXXRYNS...
25 Jul 2024, 12:16:54, EDT
Signing Reason: I approved this document

Name: Ghania Chaib

Email: ghania.chaib@thorasys.com

IP: 197.204.13.234

Location: ALGIERS, 16 (DZ)

Date: 25 Jul 2024, 09:27:10, EDT

Consent: eSignature Consent Accepted

Security Level: Email, Account Login Password Authentication

Ghania Chaib

Ghania Chaib
Signer ID: DOT5CSV9JP...
25 Jul 2024, 09:27:10, EDT
Signing Reason: I approved this document

Name: Lucas Posada

Email: lucas.posada@thorasys.com

Lucas Posada
Signer ID: VURHTIJKP1...
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

Document History:

Envelope Created	Fatima Chaouki created this envelope on 10 Jul 2024, 10:16:07, EDT
Invitation Sent	Invitation sent to Lucas Posada on 10 Jul 2024, 11:22:41, EDT
Invitation Accepted	Invitation accepted by Lucas Posada on 10 Jul 2024, 12:55:04, EDT
Signed by Lucas Posada	Lucas Posada signed this Envelope on 11 Jul 2024, 15:51:33, EDT
Invitation Sent	Invitation sent to Ghania Chaib on 11 Jul 2024, 15:51:33, EDT
Invitation Accepted	Invitation accepted by Ghania Chaib on 11 Jul 2024, 15:52:23, EDT
Signed by Ghania Chaib	Ghania Chaib signed this Envelope on 25 Jul 2024, 09:27:10, EDT
Invitation Sent	Invitation sent to Etienne Lefort on 25 Jul 2024, 09:27:10, EDT
Invitation Accepted	Invitation accepted by Etienne Lefort on 25 Jul 2024, 12:08:41, EDT
Signed by Etienne Lefort	Etienne Lefort signed this Envelope on 25 Jul 2024, 12:16:54, EDT
Invitation Sent	Invitation sent to Tabitha Jaramillo on 25 Jul 2024, 12:16:54, EDT
Invitation Accepted	Invitation accepted by Tabitha Jaramillo on 25 Jul 2024, 13:32:31, EDT
Signed by Tabitha Jaramillo	Tabitha Jaramillo signed this Envelope on 25 Jul 2024, 13:33:23, EDT
Executed	Document(s) successfully executed on 25 Jul 2024, 13:33:23, EDT
Signed Document(s)	Link emailed to lucas.posada@thorasys.com
Signed Document(s)	Link emailed to ghania.chaib@thorasys.com
Signed Document(s)	Link emailed to etienne.lefort@thorasys.com
Signed Document(s)	Link emailed to tabitha.jaramillo@thorasys.com
Signed Document(s)	Link emailed to fatima.chaouki@thorasys.com