1- Internal Audit information:

Activities Audited	**Medical Device Adverse Events and Advisory Notice Reporting Process** ISO 13485:2016: 4.2.1, 7.2.3, 8.2.2, 8.2.3, 8.3.3, CMDR 59-61.1, 61.2-61.3, 63-65.1, TG(MD)R 2002 Schedule 3 Part 1 Clause 1.4(3)(c)(i), [TG (MD) R 5.7 and 5.8, TGA Part 4-9 and the Uniform Recall Procedure for Therapeutic Goods (URPTG)]. 21 CFR 803: Medical Device Reporting, 21 CFR 806: Medical Devices; Reports of Corrections and Removals. MDSAP Chapter 4, tasks 1- 17)
Audit Date(s)	2024-06-11
Audit Date scheduled (*as per Audit schedule*)	June 10, 11, 13, 2024
Internal Auditor(s)	Gordon Forest, VL Solutions Inc.
Employees audited	Fatima Chaouki, Tabitha Jaramillo
Department Manager	Étienne Lefort

2- Audit Summary:

I have verified that Thorasys has established and maintains written procedures for reporting events related to medical devices and for the recall of these devices in various markets, specifically Canada, the United States, Australia, the EU and the UK.

Reportable events: There were no reportable events (Including Foreign Risk notification to Health Canada – no serious injury events or issues).

QMS Procedure No: QP16 Regulatory Process, rev. 9.0 has the objective to:

1 Define the regulatory processes to ensure product compliance with the regulations of the intended markets for the sale and distribution of THORASYS products.

2 Define the steps to ensure the creation and maintenance of Clinical Evaluation Reports (CERs) for CE-marked products, as required to provide the clinical performance and safety data as evidence to demonstrate continued conformity with the MDR General Safety and Performance Requirements, and, as applicable to Legacy products (i.e. products CE marked under the MDD) per Article 120 of the MDR, the continued conformity of with the Essential Requirements of the MDD.

3 Define the requirements for creating and maintaining the CERs,

4 Define the regulatory requirements for the Authorised Representative (EU), and the regulatory and quality management requirements for Importers and Distributors.

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EU Authorized Representative (EC REP)

In accordance with Article 11 of the MDR, if the manufacturer is not established in a EU Member State, as is the case currently for Thorasys, products may only be *placed on the market* in the EU if the manufacturer designates per a written contract (mandate) a Authorized Representative for the EU (called EUAR). While there can be multiple EUARs covering multiple generic device groups, there shall be a single designated EUAR for each generic device group.

The mandate shall require, and Thorasys shall enable, the authorized representative to perform tasks in relation to the devices that it covers. A representative agreement with OMC Medical (Belfast, Northern Ireland) was signed 02/10/2022.

Recall: There was one recall issued for the period under audit. It occurred in Australia and was initiated by Thorasys. The details of the recall are reported in section **Medical device reporting/vigilance report trends and corrections and removal actions of audit report Measurement, Analysis and Improvement.**

Recall procedure UK – QP27, Rev. 1.0 Medical Device Reporting UK. If field safety actions have to be implemented, QP20.

This procedure provides timelines for reporting.

Timescale for reporting:

a) Serious public health threat: immediately (without any delay that could not be justified) but not later than 2 calendar days after awareness by THORASYS of this threat.

b) Death or unanticipated serious deterioration in state of health: immediately (without any delay that could not be justified) after THORASYS established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

c) Others: immediately (without any delay that could not be justified) after THORASYS established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.

General recall process and specifics for Canada, USA, EU, Rev. 3.0. provides timelines for the EU.

3- Non-Conformities:

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

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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: HFBIXXRYNS... 25 Jul 2024, 12:16:54, EDT Signing Reason: I approved this document	Tabitha Jaramillo	25-Jul-2024 EDT
	Tabitha Jaramillo Signer ID: INFXWXQWVX... 25 Jul 2024, 13:33:23, EDT Signing Reason: I approved this document		

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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

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

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Document Ref: e4f0153e6e3c3983e69298f095766af5a9edc0186eb98890e26a801d6182ef54

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: a991dc4e3d45975521036c90e3cb066ce56e374b6512a415b0681e0196aae39f

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:

Document Ref: 3beba510df6a925fba7b5cc05328469b029c11dd914b9e48865470d09bb93668

Document Total Pages: 7

Name: Internal audit summary report - 2024 - Corrected

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Document Total Pages: 2

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