1- Internal Audit information:

Activities Audited	Internal Audit QP10 Rev. 3.0
Audit Date(s)	15-08-2024
Audit Date scheduled *as per Audit schedule)*	July 2024
Internal Auditor(s)	Fatima Chaouki
Employees audited	Tabitha Jaramillo
Department Manager	Tabitha Jaramillo

2- Audit Summary:

Standards audited:
- *ISO 13485: 2016;*
- FDA 21 CFR part 820;
- Canadian Medical Devices Regulations SOR/98-282;
- European Medical Device Regulation 2017/745 (MDR) and
- European Medical Device Directive 93/42/EEC.
- MDSAP (Canada/USA/Australia)
- UK MHRA medical device regulation 2002

For each requirement of ISO 13485: 2016 regarding the internal audits, the requirements of the above standards were also verified.

The organization shall conduct internal audits at planned intervals to determine whether the quality management system (ISO 13485 8.2.4):
a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;
b) is effectively implemented and maintained.

The internal audits schedule for all THORASYS processes were defined as per 2024 schedule approved by QA on 12-12-2023. The processes are audited once a year.
The Internal audits (except the internal audit of the internal audit process) for 2024 were performed in June 2024 (audits were scheduled for July 2024).

Quality objective (audit to be performed within 3 months from their initially scheduled time) was met.

The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results (ISO 13485 8.2.4).

The procedure Internal Quality Audits QP10 Rev 3.0 (effective on 21-06-2023) was reviewed; the responsibilities for managing the internal audits are defined for the Quality Assurance department, the Internal Auditors, and the Manager of the Audited Department.

An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (ISO 13485 8.2.4).

As per QP10 Rev 3.0, the Quality Assurance is responsible to prepare a yearly schedule.

Internal Audit Schedule for 2024 was verified: the internal audits were planned once a year for all THORASYS processes; the schedules were approved by QA/RA Manager on 12-12-2023 before starting to perform the planned internal audits.

THORASYS 2024 internal audit schedule list the procedures to be audited, the due date of the audits and the reference to the standards that will be covered during the internal audits.

Note that the internal audits of 2024 were performed by a third party and the agenda plans defined by them (Thorasys 2024 Internal Audit Schedule VL Solutions) covered all the requirements that must be audited.

The requirement is met.

The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work (ISO 13485 8.2.4)

As per QP10 Rev 3.0 the internal audit has to be performed by the internal auditor who is trained on the internal audit procedure and/or by qualified external auditors trained as an ISO 13485:2016 and MDSAP auditor.

QP10 Rev 3.0 indicates also that quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited.

The internal audits were performed by qualified supplier (VL Solutions) and specifically by Mr Gordon Forest (form VL Solution) for all THORASY processes in 2024 (except for Internal audit process).

Gordon Forest has completed the following certificates:
- Medical Device Regulatory Requirements (completed on 2018)
- MDSAP (completed on 2021)
- MDR 2017/745 (completed on 2020)
- MDD (completed on 2018)

Internal audit of the internal audit process in 2023 was performed by Fatima Chaouki (QA consultant) qualified as per her quality assurance experience*.* See Fatima Chaouki Vendor Qualification.

The requirement is met.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (ISO 13485 8.2.4).

Followings 2024 Audits reports were reviewed: :

- Internal Audit Report Design and Development Process - June 2024;
- Internal Audit Report Marketing Authorization - June 2024;
- Internal Audit Report Measurement Analysis and Improvement - June 2024;
- Internal Audit Report Medical Device Adverse Events and Advisory Notice Reporting Process - June 2024;
- Internal Audit Report Production and Service Controls Process - June 2024;
- Internal Audit Report Sales and Purchasing Process – June 2024
- Internal Audit Summary Report 2024.

The requirement is met.

For the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (ISO 13485 8.2.4).

As per QP10 Rev 3.0, a CAPA request is initiated by QA for all NCs (major, medium, and minor)

The NCs and OFIs resulting from the 2023 internal audit of internal audit process and 2024 internal audits:

→ 2023 (Internal Audit Process):

No NCs were raised and therefore no CAPA was opened

Noted: The actions status for all the others audited process in 2023 were reviewed during the 2023 internal audit of the internal audit process.

→ 2024:

No NC was raised and therefore no CAPA was opened.

21 CFR 820.22 Quality Audit: Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

The procedure Internal Quality Audits QP10 Rev 3.0 (effective on 21-06-2023) was reviewed; the responsibilities for managing the internal audits are defined for the Quality Assurance department, the Internal Auditors, and the Manager of the Audited Department.

The quality audits were performed by an internal auditor who do not have direct responsibility for the matters being audited.

A report of the results of each quality audit, was performed and these reports were reviewed by the appropriate managers.; the dates and results of quality audits were documented in each audit report.

3- Non-Conformities:

No NC raised.

4- Opportunities For Improvement:

No Opportunities For Improvement raised.

Documented /Approved by	Name:	Signature:	Date:
Department Manager			
		Tabitha Jaramillo Tabitha Jaramillo Signer ID: INFXWXQWVX... 19 Aug 2024, 12:49:47, EDT Signing Reason: I approved this document	19-Aug-2024 EDT
Quality Assurance			
		Fatima Chaouki Fatima Chaouki Signer ID: B2RTKVG777... 19 Aug 2024, 14:01:44, EDT Signing Reason: I approved this document	19-Aug-2024 EDT

Signature Certificate

Envelope Ref:f94d11e96b6c58cd21796efbcfc6717395c393ef

Author:	Fatima Chaouki	Creation Date:	19 Aug 2024, 12:47:08, EDT	Completion Date:	19 Aug 2024, 14:01:45, EDT

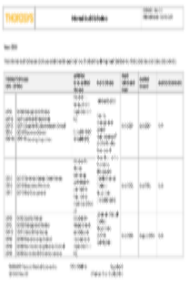
Document Details:

Name: 2024 QF10-01 Rev 1.0 Internal Audit Process

Type:

Document Ref: ab6c75f428f980f46e8ae353877cc84c8bbb5dd3c16d29fc5e907f9b99a80b1a

Document Total Pages: 5



Name: Internal Audit Schedule 2024

Type:

Document Ref: 66eb329b424dad59eba87bd3723700ca949fee72a93a3c5648d99abe07738446

Document Total Pages: 4

Document Signed By:

Name:	Tabitha Jaramillo
Email:	tabitha.jaramillo@thorasys.com
IP:	69.70.57.54
Location:	MONTREAL, QC (CA)
Date:	19 Aug 2024, 12:49:47, EDT
Consent:	eSignature Consent Accepted
Security Level:	Email, Account Login Password Authentication

Tabitha Jaramillo
Tabitha Jaramillo
Signer ID: INFXWXQWVX...
19 Aug 2024, 12:49:47, EDT
Signing Reason: I approved this document

Name:	Fatima Chaouki
Email:	fatima.chaouki@thorasys.com
IP:	142.115.3.194
Location:	MONTREAL, QC (CA)
Date:	19 Aug 2024, 14:01:44, EDT
Consent:	eSignature Consent Accepted
Security Level:	Email, Account Login Password Authentication

Fatima Chaouki
Fatima Chaouki
Signer ID: B2RTKVG777...
19 Aug 2024, 14:01:44, EDT
Signing Reason: I approved this document

Document History:

Envelope Created	Fatima Chaouki created this envelope on 19 Aug 2024, 12:47:08, EDT
Invitation Sent	Invitation sent to Tabitha Jaramillo on 19 Aug 2024, 12:48:18, EDT
Invitation Accepted	Invitation accepted by Tabitha Jaramillo on 19 Aug 2024, 12:48:57, EDT
Signed by Tabitha Jaramillo	Tabitha Jaramillo signed this Envelope on 19 Aug 2024, 12:49:47, EDT
Invitation Sent	Invitation sent to Fatima Chaouki on 19 Aug 2024, 12:49:47, EDT
Invitation Accepted	Invitation accepted by Fatima Chaouki on 19 Aug 2024, 14:01:29, EDT
Signed by Fatima Chaouki	Fatima Chaouki signed this Envelope on 19 Aug 2024, 14:01:44, EDT
Executed	Document(s) successfully executed on 19 Aug 2024, 14:01:45, EDT
Signed Document(s)	Link emailed to tabitha.jaramillo@thorasys.com
Signed Document(s)	Link emailed to fatima.chaouki@thorasys.com