REPORT

SYSTEM AUDIT - STAGE 2
ISO 9001:2015

STERIS AUSTRALIA PTY LTD

9 ARCO LANE,
HEATHERTON,
VIC 3202 AUSTRALIA

AUDIT DATE
FROM: 17-FEB-2025 TO 21-FEB-2029

REF NO. 50000373

DQS Certification AUSNZ Pty Ltd
480 Collins Street, Melbourne, Victoria, 3000 Australia

1 Certification recommendation

Thank you for your trustful cooperation during our recent audit of your organization. This report details the audit results including strengths, opportunities, and weaknesses. These results were presented to your management at the closing meeting of the audit. You can use these results to improve the effectiveness of your management system. We look forward to continuing our partnership towards sustainable business success.

In reference to ISO 9001:2015, the audit team recommends to DQS:

☐ Issuance of the certificate
☒ Issuance of the certificate as soon as implementation of corrective actions has been demonstrated
☐ Maintenance of the certificate
☐ Maintenance of the certificate as soon as implementation of corrective actions has been demonstrated
☐ Not applicable, due to extraordinary type of report

Disclaimer Statement

All audit findings are based on a sampling process, targeted towards reliable evidence for effective implementation and compliance of the management system. Where applicable findings and required corrective action plans were or will be agreed upon with the responsible managers or management representatives, steps have been or will be defined to
resolve such non-conformity. Further business aspects may exist, positive or negative, which have not been reviewed by the audit team. It is the organization´s responsibility to investigate and evaluate the potential impact and scope of findings, thus continuously ensuring full compliance to the applied standard(s).

Please remember to notify DQS about any significant change to your management system at your earliest convenience. Together we will then coordinate appropriate measures to maintain your current certification.

1.1 Management system – past performance

Year	ISO Reference	Description
2025	ISO 9001:2015 Cl 7.5.3	Control of external documents
	ISO 9001:2015 Cl 7.5.3	Release of products and services

2 The Management System

2.1 Evaluation

DQS Assessments apply the Plan – Do – Check – Act, or the PDCA cycle approach. It can be applied to individual processes, a system or a managed organization.

Plan: Activities are planned objectives, processes and resources

Do: The plan is implemented.

Check: Results are compared with objectives and expectations.

Act: Necessary improvements and change are defined and planned (see Step 1. “Plan“).

In summary we have evaluated your management system as follows:

2.2 Executive summary

This Initial – Stage 2 audit was done onsite at Heatherton VIC by the auditor. Based on Steris’s ISO 13485:2016 certification history and the planned transition to a QM-only system, no additional Stage 1 audit was deemed necessary.

Additional site Steris New Zealand #50000690 has been audited remotely for 0.5 day and the ICT used was effective.

The activities performed at Steris New Zealand are limited to the site and the site remains under the control of the head office location in Heatherton VIC.

The structure of the audit was in accordance with the audit plan.

The auditor conducted a process-based audit focusing on customer requirements, standard's requirements and company procedures. The audit methods used were interviews, observations, sampling of activities and review of documentation and records.

The auditor confirms that the audited company has implemented and maintains a management system in accordance with the applied standard of ISO 9001:2015. Detailed audit results were presented, explained and, as necessary, discussed with the organization's management during the closing meeting.

The following chart provides a graphic overview of the respective audit findings and evaluations:

No	Process	Standard	Requirement	Verified during audit Y = Yes N = No	Conform Y = Yes P = Partially N = No	Evaluations Str = strength OFI nc NC 0 = neutral
1	*Operational planning during service/installation*	*ISO 9001:2015*	*8.1*	*Y*	*Y*	*Str*
2	*Context*	*ISO 9001:2015*	4.1, 4.2	Y	*Y*	OFI
3	*Management Review*	*ISO 9001:2015*	9.3.2	Y	*Y*	OFI
4	*Release of services/products*	*ISO 9001:2015*	8.6	Y	P	nc
5	*Control of External Documents*	*ISO 9001:2015*	7.5.3	Y	P	nc

Nonconformities identified during the audit must be demonstrably and effectively closed within the established period (see chapter 5). Identified potential for improvement should be evaluated by the organization and, if necessary, used for continuous improvement.

nc = minor nonconformity, NC = Major nonconformity, OFI – Opportunity for improvement

During the audit the following findings were identified

Type	Area/Process	Clause
Minor	Control of external documentation	7.5.3
Details:	No evidence could be sighted at the time of the audit regarding applicable NZ regulatory requirements. IE The Medicines Act 1981 as well as Australian Biosecurity requirements IE. Biosecurity Act 2015 identified as applicable needs to the business.	

Type	Area/Process	Clause
Minor	Release of products and services	8.6
Details:	The release of products and services is not effective in that a)P764340-151 R2, Advantage Plus Pass Through Equipment Startup Checklist for Serial 13139388 It's not know as to the validity of the monitoring devices used to measure the water temp, water pressure, compressed air pressure and input voltage are compliant to requirements. b)P764337-159 R4 AMSCO V-PRO maX 2 Equipment Startup Checklist dated September 2024. No evidence was sighted on the record for the correct power requirements being met.	

Type	Area/Process	Clause
OFI	Organisational Context	ISO 9001 Cl 4.1, 4.2
Details:	Consider the how or if climate change is an applicable internal/external issue to the business, and furthermore, consider of such climate change articles have an impact on your relevant interested parties in accordance with amendment 1:2024 of ISO 9001	
Statement of why OFI is not classified as NC	The organisation has identified the requirement in the list of external standards but has not yet implemented them. DQS offers a grace period for the transition into amendment 1.	

Type	Area/Process	Clause
OFI	Management Review	ISO 9001 Cl 9.3.2
Details:	Consider revisiting the management review data once the new process has been implemented.	
Statement of why OFI is not classified as NC	The requirements of the review inputs are seen within the meeting minutes; however, the organisation is developing a local procedure, via CHNG-009, to better align the process with ISO 9001. The current global process is driven around ISO 13485.	

Given this the following strength was also identified.

- Excellent operational planning with respect to the service and installation activities due to the integration of manufacturers processes and requirements within the process.

It is understood that the audit was conducted using a judgement-based sample approach, as such, some level of uncertainty is accepted during the audit process.

Furthermore, it is understood that the recommendations and findings presented within this report is subjected to technical review and approval.

The auditor would like to thank the audit team for their openness during the audit program.

2.3 PLAN: The management system and objectives

Internal and external issues within the organisation are managed within a live platform via the change management process for opportunities, and Risk Management, for risk issues within the business.

- Sighted ANZ Change Management (living document)
  The platform documents the kind of changes (opportunities), an analysis of impacted interested parties, information about the kind of opportunities addressed.

As part of these changes, an additional spreadsheet is indicated within the living platform that addresses risks within the changes.

Examples of changes, and as such opportunities include.

- Change 005 for the website change to the Australian business. (similar articles are seen within the Change for the NZ007 business website).
  Impacted parties include marketing, regulatory, sales, technical services.
  Actions for the change
- Change 002 CRK NZ Acquisition.
  The change was the acquisition of Steris products/services within the NZ market.
  Actions to drive the changes included regulatory works, with respect to product registrations and changes, customer notifications to inform acquired customers of the changes, internal technical services for parts transfer.

In a pragmatic approach, internal/external issues, interested parties, as well as risks/opportunities are realised within various elements of the business, including the sales processes, where monitoring and analysis activities for each business unit are conducted.

Type	Area/Process	Clause
OFI	Organisational Context	ISO 9001 Cl 4.1, 4.2
Details:	Consider the how or if climate change is an applicable internal/external issue to the business, and furthermore, consider of such climate change articles have an impact on your relevant interested parties in accordance with amendment 1:2024 of ISO 9001	
Statement of why OFI is not classified as NC	The organisation has identified the requirement in the list of external standards but has not yet implemented them. DQS offers a grace period for the transition into amendment 1.	

- Sighted February sales analysis data.
  Data shows interested parties considered as competitors with an issue of the party undercutting on price.
  As such discussions are seen with risks and opportunities to review pricing to negate such issues.

A risk register (within the live platform tool) is presented showing risks (issues to the business.

Changes are reviewed during the development of the change activity. This requires an independent authority for changes. Marketing and Quality functions approved the above change/s.

Risks are reviewed in the audit include RSK-001. The risks were indicated with import approval of biological products into NZ, due to changes within the regulatory body.

Note that the risk register is only newly developed to meet the intent of the international standard, as such, only 3 risks are indicated (refer to risk discussions).

Interested parties are considered within the change piece. When developing changes, the need to assess interested parties and their requirements are considered. Refer to the above discussions.

A quality manual is presented, Q01-QSE-000001 (v9) STERIS Quality Manual, to indicate the scope of the management system.

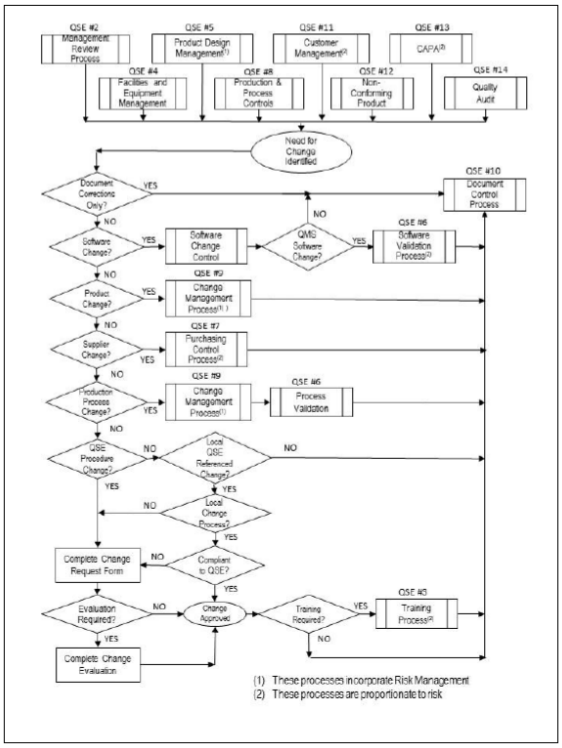
The manual indicates that the system falls under the global management system and covers operations of all parent and daughter companies.

The organisation covers sales, distribution and service activities. Falling under the healthcare business unit, the applicability of elements within the management system (global) are indicated.

This is exemplified within the following document.

- Sighted Q01-LS-000001 R44 Quality Manual Exclusions, Non-applicable Clauses and Site listings.
  The document shows the intent of the management system with respect to the applied standards as well as the relevant non-applications.
  Both the NZ Site and Australian site indicate that Distribution and Servicing is within the scope of activities.
  Non-applications to the system include only design and development activities.

A process interaction map is established within the quality manual, however this is more management system focused



This is supplemented by the overall document register.

- Q-00573 R2 FRM0001 ANZ Master Document List
  The document shows the interaction of the documented processes around the requirements of the international standard, as well as global processes, that the organisation needs to adhere to.
  Any locally developed processes are supplemental to the global requirements.

Performance measures for core process are indicated and monitored within the Management Review Meeting minutes.

These include indicators for

- Service (70%)
- Supply Chain (95% DIFOT)
- Regulatory Reporting (on time)

This is complimented by the Quality Objectives. (refer objectives discussions).

Top management show commitment to the management system through

- The development of policies and procedures (refer policy)
- Development of Objectives (refer management review)
- Establishing a processed based approach (refer Q-00573 R2 FRM0001 ANZ Master Document List) which includes customer related processes and the integration of global and local processes.

- Awareness through the business, via functional heads (also considered top management).

Top Management is defined within the organisational chart

- Sighted STERIS Org Chart_ANZ_Jan25

  Top management is considered the functional heads of each department, also consisting of NZ functions.

Roles and responsibilities within the business are defined at a macro level within the quality manual Q01-QSE-000001 (v9) STERIS Quality Manual, Section Management Responsibilities. The role and responsibilities of top management and function level managers are indicated as well as their commitment to the management system.

The manual expands on the definition of top management by stating Senior Management Team (SMT) includes the individuals noted above plus the Senior Executive Board (SEB) and other senior Business Leaders designated by the President and Chief Executive Officer of STERIS

A policy is provided within the quality manual, Q01-QSE-000001 (v9) STERIS Quality Manual P6

Awareness to the policy is made through the digital training platform (refer to competence discussions).

External to the business, the policy is distributed on demand.

The policy establishes objectives framework through “offering value, quality, and reliability that exceeds their expectations”

Links to objectives can be seen within service quality and reliability, as well as expectations in DIFOT.

A commitment is seen to improving the management system as well as a commitment to applicable “laws and regulations”

Applicable laws and regulations include

- Medsafe NZ
- TGA(MD)Regulations
- Biosecurity Act

laws and regulations Objectives to the management system are planned for, documented, and discussed within the management review meeting minutes.

- Sighted B01-TM-001 Version: 1. Management Review Meeting Minutes dated Novemnber 2024

  Objectives include the following

  1. Support STERIS ANZ ISO 9001 Certification, Internal and External Audit.
  2. Minimize the nonconformities from 3 to 2.
  3. Maintain an average number of calendar months (i.e., 6 months) that meets DIFOT benchmark, e.g. 95%
  4. Achieve 70% of timely preventive maintenance tasks for Technical Services.

Risks and opportunities to the business are identified and documented. The concept of QMS risks is novel to the business under ISO 9001, as such, the process is only new.

The management system manual indicated that risk management activities are incorporated into the appropriate Quality System processes (e.g., Product Design Management, Nonconformance, CAPA, etc.).

Risk-based thinking is utilised in the development and maintenance of QMS processes to:

- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective
- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
- Implement actions necessary to achieve planned results and maintain the effectiveness of these processes
- Monitor, measure as appropriate, and analyse these processes
- Establish and maintain records needed to demonstrate compliance with the QMS and applicable regulatory requirements.

Risk management is incorporated in the following Quality System Element (QSE) processes:

- Product Design Management and/or
- Change Management and/or

- Execution of Customer specifications

A risk register (within the live platform tool) is presented showing risks

- Sighted Risk Register (living document)
  3 risks are currently presented.

RSK-001. The risks were indicated with import approval of biological products into NZ, due to changes within the regulatory body. Controls for the risk include escalation with MPI (NZ regulator) and increase the buffer time for product imports, monitor the situation of imports.

- Sighted Import Tracker (living document) showing updates and import times. Relevant calendar invites are established as a reminder to import permits.

RSK-002 Legal manufacturers name change risks from Carefusion to St. Louis ARTG legal manufacturer.

https://compliance.health.gov.au/artg/

Controls include the drafting of a letter to the TGA in order to reflect and notify of the changes.

Resourcing within the business is determined at a global level for people, this is fed from local SLT level.

When headcounts are requested from a function management level, this is fed into SLT and then through to global businesses for actioning and decisions.

Similarly, the SLT discusses infrastructure requirements for the in-scope offices.

- Sighted Financial Year Plan FY26 Plan
  The discussions are hosted around IT infrastructure improvements within the facility.

On top of this the management review provides a macro level forum for the input of resources into the management system.

Overall the process for resource management is defined within an overarching procedure.

- Sighted SOP-00059 Rev E, ANZ Resource Management

From a micro level, processes are put in place to determine the resourcing and infrastructure requirements.

- Sighted Q04-003 R3, Environmental Controls
  The document is provided to outsourced processes to indicate the resource and infrastructure requirements for storing Steris products.
- Q04-001, R4Control of Monitoring and Measuring Equipment
- SOP-0078 Rev E, STERIS ANZ Calibration of Measuring and Test Equipment

Outsourced resources are also available for the storage and distribution of Steris products. These are managed as vendors. Refer to the Vendor management discussions for controls around this inspection element.

Awareness to the management system is provided to staff through the training system.

A training matrix is put in place to identify the processes and policy's function/function units are required to undertake.

The matrix is supported by a documented training procedure.

- SOP-00057 Rev E, STERIS ANZ Training Procedure
  The procedure looks at the training requirements and the developments of competence requirements for each staff including macro level needs (typically as Job Descriptions) as well as corporate requirements determined within the training matrix.

Records of training are maintained within Propel.

Job descriptions and evidence of compliance are maintained within the HR department, omitted for confidentiality.

- Sighted Q-00571 R3, ANZ Training Matrix
  The matrix lists various training plans.
  TP-03315, indicated for all employees includes procedures for
  - oQ02-001 Management Review
  - oQ001 Quality Manual
  - oTRN-00001 QMS Training
  - oSOP-00379 Supplier Controls
- TP-00602 Technical Services staff

- oSOP-0009 STERIS ANZ Installation and Service Controls.
- oSOP-0078 STERIS ANZ Calibration of Measuring and Test Equipment

The following training records were assessed as part of the audit.

- Field Service Engineer MD
  - oSighted Training Report (12 Feb 2025) ran annually, showing training for the following
    - ▪ TP-00602 – Completed
    - ▪TP-03315 – Completed
- National Sales Manager FC
  - oSighted Training Report (12 Feb 2025) ran annually, showing training for the following
    - ▪SOP00561 Rev A – Completed
- Supply Chain Manager ANZ AJ
  - oSighted Training Report (12 Feb 2025) ran annually, showing training for the following
    - ▪WI-02481 Rev A – Completed
    - ▪TP-00603 – Completed
- Field Service Engineer AE
  - oSighted Training Report (12 Feb 2025) ran annually, showing training for the following
    - ▪TP-00602 – Completed
    - ▪TP-03315 – Completed

Communication, internally, is maintained through various meetings (planned, unplanned, documented and undocumented.)

This includes customer facing meetings and planning meetings.

- Sighted B01-TM-001_1_ANZ Management Review_Nov24
- Sighted Financial Year Plan FY26 Plan

External communication is managed through the change management process.

Examples of this are seen within the change management process.

- Change 002 CRK NZ Acquisition, where communication letters were identified as an output action to notify customers.

In addition to these dedicated processes are put in place regulatory communication.

- Sighted WI-02487 R8, SERIS ANZ Recall Process.
  The procedure indicates the methods of communication, timelines, and communication requirements based around the TGA uniformed recall and NZ Medsafe procedures.
  This includes the interface between the global legal manufacturer forms, where the local offices are responsible for regulator notification (from the manufacturers recommended actions) as well as customer notification.

A procedure is available for the control of monitoring and measurement equipment.

- Sighted Q04-001 R4, Control of Monitoring and Measuring Equipment
  The global procedure is supplemented by a local document
- Sighted SOP00078 Rev E, ANZ Calibration
  The process requires records to be verified by STERIS staff upon acceptance. Furthermore, measurement traceability is required to a national/international standard (as applicable and where available). When failures are found, a CAPA is to be raised to investigate the validity of prior measurement results.

Information around calibration requirements of assets are indicated on the calibration register. A register is maintained for each state.

- Sighted VIC FRM-00088 Rev C, ANZ Calibration Register
  Both inspected devices below are indicated on the register and align with marked calibration dates.
- Sighted WA FRM-00088 Rev C, ANZ Calibration Register
- Sighted NZ FRM-00088 Rev C, ANZ Calibration Register
  The following appeared on the schedule.
  Scales Asset STNZAKL-10 Serial 190032417 to be calibrated annually due 16/4/25

The following device was noted as being used on the installation of Serial 13144422 Advantage Plus Seibel Service Request Number 1-8266281807,

Manometer Serial 21240481 Asset CAAUVIC#15.

- Sighted FRM-02485 ANZ Equipment Verification Check record dated 18/10/2024 for manometer Serial 21240481 using Serial1914708 (gold standard manometer).

The acceptance criterion for the manometer is as recommendations within the equipment user manual.

- Sighted Diagnostix Aneroids Picket, Palm, Clock Type.
  The document indicates +/- 3mmHG. The recommended verification frequency is 24 months.

The gold standard manometer is verified by an external party (TR Calibrations). A certificate is provided.

- Sighted TR Calibrations Report 24.1100484 for manometer Serial 1914708
  The record does not indicate that adjustments were made to the device.
  The certificate shows traceability to national standards.
  The record was authorised by STERIS staff as per the planned arrangements.

- Sighted Wedderburn Scales 8002621-1
  The report shows traceability to the reference standards used to execute the testing.

A document control system in place managed by the software tool “Propel” (Salesforce module)

The organisation is transitioning in TrackWise (alternate computer system).

Some documents are managed and owned by global teams, as such, the local teams may review the documents and provide feedback.

In these cases, document preservation, retention, opalescence is controlled by the global team.

Local documents are preserved through computer system “Propel”.

When the need for local documents updates or creation is required, it’s done using a global procedure, adopted with local requirements (for example the eQMS system needs)

- Sighted Q10-001 R4, Document and Record Controls

Function management are responsible for the review and approval of relevant documents.

All documents are preserved and retained in an electronic format. A review period of 3 years is required for all document used within the QMS.

Documents of external origin are indicated on a document list, and it is the responsibility of the user of such documents to ensure the currency of said document.

- Sighted an external document list, Q01-LS-000002 R20, Quality Manual Applicable Standards and Regulations.
  Examples include
  ISO 9001:2015 +AMD1 2024.
  Therapeutic Goods (Medical Device) Regulations 2002

Type	Area/Process	Clause
Minor	Control of external documentation	7.5.3
Details:	No evidence could be sighted at the time of the audit regarding applicable NZ regulatory requirements. IE The Medicines Act 1981 as well as Australian Biosecurity requirements IE. Biosecurity Act 2015 identified as applicable needs to the business.	

Retention periods are determined and documented within a defined schedule

- Sighted BCP-104.1a R5, Master Record Retention Schedule
  Retention dates include;
  - oRecords of approval of process and procedures - Permanent retention
  - oCustomer Operation Training Records – 3 years
  - oPeriodic Maintenance Records – Permanent retention
  - oPurchasing Records – 5 years
  - oReturned Goods Records – 5 years

- Internal Audit – 7 Years
- Installation/Service Records – Permanent retention

Document change orders are required to initiate changes or new documents.

- CO-17475 for the update to ANZ technical services QMS documents

  Justification of changes is provided as well as planned document changes.

The document changes are packaged with the change order, as such, when the change order is approved, then the documents are also approved.

Once the documents are approved, the final stage of the document lifecycle is implementation and training in accordance with the impact assessment (for the change).

Documents are met with revision controls such as history tables, version numbers, document numbers, evidence of review and approval.

The software tool manages version control where superseded versions are removed for consumption. Similarly, persons trained on prior versions are also issued training.

Examples include SOP-00056 STERIS ANZ Installation and Servicing Training Procedure Rev D replaced revision D of the Cantel (Australia) procedure.

2.4 DO: Processes in operation

Operational planning is considered uniformed across the management system, as such, it is managed from the head office.

Examples include vendor management activities being driven through head office.

The internal audit programme is also driven from global, using unified procedures, however, considered as part of the same audit report and activity.

Procedures and operational planning are unified across both sites.

Operational procedures are an output of planning and risk tools (within change, risk assessments, and CAPA outputs).

Core Process – Sales

Opportunities are presented within 3 avenues. The process is the same for t

1-Tender based
2-BDM opportunities
3-Adhoc opportunities

No formalised processes are maintained, however the computer system maintains controls of opportunities.

Quotes are developed through the software tool post discussions with the clients.

- Sighted Quote Number WACHAN1734839.

  Links are seen to the customer, the items required, the discounts and pricing. Terms and conditions are indicated on the final issued quotations.

Monitoring is provided within the software tool in the event of lower margins or in the event of a free of charge.

As such, managers are required to approve the quotation.

The formal quotation is presented to the customer. A formal Purchase Order is receipted from the customer.

Customer Services teams will confirm the order with the Sales Representative.

In the event of tenders. One manager in each state is responsible for monitoring tender requests/opportunities.

A process is provided for the tender management issue.

- Sighted SOP00561 Rev A, ANZ Tender Process.

A SharePoint site is provided for the management of tender documents and information.

The file structure includes the tender documents, STERIS responses and other related information.

- Sighted tender documents for Aegis Health (Murdoch Campus in WA).
  Information includes submission, presentation files, and agreements.
- Sighted Aegis Health PO AH-000001 linking to the above tender sales.

Consumables changes from customers are communicated to the sales team by the customer. This is fed in to monthly demand meetings post discussions with customers.

Forecasting is based on customer knowledge, the kinds of consumable are required for each

- Sighted Consumables Forecast dated 12 February 2025
  The forecast indicates the quantity of parts that should be maintained within the warehouses.

In the event of sudden changes or supply chain issues, the organisation works with Supply Chain teams to meet resource demands.

As best practice a safety stock of critical products on hand to ensure continuity.

This is to ensure that the business has the capacity to service the customers.

A corporate site (available to internal staff) provides information to internal staff about products and consumables including specification, product brochures, tips on products.

- Sighted STERIS Hi-Spot/SRC website.

Evidence of customer acceptance of orders is maintained in accepted agreements or provided purchase orders maintained on SalesConnection (linking into Oracle).

- Sales Order 17813007 for the sales installation of Serial 1314442 Advantage Plus

Core Process - Sales/Installation.

An overarching global procedure is made available for the installation and service activities of Steris products.

- Sighted Q08-005 R3, Handling, Storage, Distribution and Installation

This is supported by Q01-QSE-000008 R3, Service Controls

Again, these are supplemented with a local procedure. The intent being that any information that does not present within local procedures should be referred to in the higher-level procedures.

- Sighted SOP-000067 Rev D, Installation.
- Sighted SOP-000070 Rev E, Servicing.

  Note that some elements of the service or installation activities may be subcontracted, this includes electrical or plumbing installation.

In essence, the service team take the project over once the sales department have arranged delivery of the products to site.

Information around the installation/service timelines are discussed with the customer. This can be driven from the sales team or directly via the sales team to the customer, depending on relationships with the customer.

Monthly meetings with the sales teams are in place to choreograph the service and installation activities with sales/customers, as well as realising opportunities. This prevents unintended commitments are made to the customers and resource planning is achieved.

- Sighted Monthly Installation Resource Allocation meeting invite, scheduled for 4th February 2024.
  Once planning is committed, then customers are notified. This may involve meetings with any particular project management site.
  This may include any particular onboarding requirements that are site specific that include
  - Industry induction
  - Site specific inductions.

  Monthly planning meetings include attendees for the NZ site, as such, planning includes NZ installation and service activities.

Installation/service manual along with relevant installation/service checklists are provided by the manufacturer and are maintained on SharePoint and KMS (Owned by global office). This ensures that local service/installation teams have access to the latest revision of the installation materials.

Siebel (computer software) us used to attach Service request number and to trace and identify the equipment to the customer.

This also maintains installation and service history and records of engineers that were used to execute the service activities.

- Sighted Seibel Service Request Number 1-8266281807

Installation of equipment Serial 13144422 Advantage Plus

- Sighted P76340-152 R2, Advantage Plus Equipment Startup Checklist for Serial 13144422 dated 24/9/2024
  The checklist maintains the criterion for pass of fail of several installation elements determined by the manufacturer as being critical to operations.

Links within the SIEBEL record relate back the sales order for which the equipment was procured.

- Sales Order 17813007

Specific installation requirements are presented to the customer indicating utilities needed to service the equipment

- Sighted 500098-1520 Installation Package - Site Requirements (Manufacturer document located on SKM and exemplified during the audit.
  Objective evidence is sought for the requiremetns, from the customer, but may not be attained.
  STERIS seeks to communicate with the customer prior to executing the installation.
  Discussions with Technical Services Dierector suggests risks to installation requiremetns are not typically high and can be managed, if any.

Installation requirements indicate the use of manometer for the verification of installation parameters. Identification of the unit is not made on the record; however, the manometer asset number is linked solely to the FSE. Refer to control of calibrated equipment discussions.

Identification of the Field Service Engineer (FSE) responsible the installation is documented within SIEBEL computer program.

- Sighted SIEBEL Record 1-8266281807 showing MD as the FSE for the installation.
- Sighted SIEBEL Service Request Number 1-8262584586
  The service request is linked to Sales Order 17754047
- Sighted P764340-151 R2, Advantage Plus Pass Through Equipment Startup Checklist for Serial 13139388
  The installation was conducted by FSE MD. As such a manometer was used to verify the above installation requirements (refer to control of monitoring equipment requirements.

The following service record was assessed for the NZ office.

- Sighted Seibel Service Request Number 1-8083350641
  Installation of V-Pro Serial 031922320 in accordance with Sales Order 17138233
  The SEIBEL record indicates FSE CW conducting the installation.

Records of installation and acceptance criteria are maintained within the SEIBEL computer program as required by the procedure.

- Sighted P764337-159 R4 AMSCO V-PRO maX 2 Equipment Startup Checklist dated September 2024.
  The record indicates a requirement to check the load and unload setpoints for the onboard compressor. Furthermore, the installation checklist indicates verification of the 3phase power supply against a target range.
- Sighted 10085694 Rev C, V-PRO Max 2 Installation Instructions
  The installation instructions indicate the relative power requirements for the unit within Asia region.

The service schedule is maintained in the SEIBEL in accordance with the manufacturer's recommendation.

Prior to the end of a equipment warranty period, service departments approach the customer to determine the need for an ongoing service contract.

Service types can include a comprehensive or preventative option at all.

If the customer agrees to a service contract, then a formal quotation is used.

- Sighted Quotation 1-7396206940/2 for the comprehensive service between 12 months for Ansco 7053HP serial 3600421007.

If the quotation is accepted, a PO is provided.

- Sighted email Northwest Private Hospital (dated 12/6/2024)
  Indicating the acceptance and associated Purchase order.

The equipment is setup with a service contract 1-7396206940/2.

- Sighted SIEBEL equipment number 1-6226451541
  Serial number 3600421007 Ansco 7053HP.
  The item is required for 4 PM's in 12 months.

The service frequency is established manually from the manufacturer recommendations.

- Sighted KMS (online portal owned by the manufacturer)
  The record for Ansco 7053HP showing 4 service intervals annually as well as the recommended time per inspection and consumables to be used.

In the event of the equipment service requirements being changed, for example the sale or decommissioning of equipment, a form is sent to the customer for review and modification of the service schedule.

The following service record was assessed.

- Serial number 3600421007 Ansco 7053HP.
  For each service inspection SIEBEL Creates a service number.
- Sighted 1-8072334962 for inspection service performed on the above equipment.
  The service was executed by Adrian H.
  Records are indicated that the service was carried out in accordance with the sighted manufacturer's checklist.

The following PM was observed that required a quotation and PO for service articles.

- Sighted SEIBEL Service Request 1-7889024976 T20m Mobile Operating Table.
  A part quotation was generated ALRUSSELL1699504
  The quotation for parts is maintained as part of the service records.
- Sighted email dated October 2024 to the customer presenting the quotation.
  A PO is receipted from the customer on 16 October 2024.
  Refer GA-011905 purchase order from the customer. As acceptance of the quotation.
- Sighted PMCL 4043-1 T20 Series of Mobile Operating Table
  The record indicates several non-compliant items including leaking gas struts, rubber seals as well as battery failures (due to age).
  The FSE was indicated as RC.

In the event of the checklist failures, the FSE then places commentary within the SIEBEL record on the resolution of the problem.

The following service data was provided for the NZ part of the audit.

- Sighted SIEBEL Request 1-8142843496.
  AMSCO 7053HP serial 3623623015. The record indicates that the service was performed by FSE AE.

The service activities were performed in accordance with a manufacturer provided checklist.

- Sighted P764337-663 Rev D, Amsco 7052HP-7053HP Washer Disinfector. Dated 10 March 2023.

Type	Area/Process	Clause
Minor	Release of products and services	8.6
Details:	The release of products and services is not effective in that a)P764340-151 R2, Advantage Plus Pass Through Equipment Startup Checklist for Serial 13139388 It's not know as to the validity of the monitoring devices used to measure the water temp, water pressure, compressed air pressure and input voltage are compliant to requirements. b)P764337-159 R4 AMSCO V-PRO maX 2 Equipment Startup Checklist dated September 2024. No evidence was sighted on the record for the correct power requirements being met.	

A global procedure is provided for the management, selection, evaluation and re-evaluation of vendors used.

- SOP-00379 Rev G, Supplier Controls

Vendors selected for input into the process are limited to products who impact product quality.

Risk classifications are applied to vendors. A criterion is provided within the procedure.

Quality agreements are required for outsourced processes.

Level 1 – high risks direct impact. As such Vendors need to be audited. Agreements are required.

Level 2 – Medium risk, indirect impact. As such, Quality Agreements, QMS certification or supplier survey.

Level 3 – Low risk. No impact or the performance and safety of the finished product. Evaluation only

The following vendors were assed at part of the audit trail

Mainfreight

Considered a risk level 2

- Sighted Supplier evaluation form dated August 2023 (initial evaluation).
  - Sighted Supplier Quality Agreement for Mainfreight dated October 2023.

TSS

Considered a risk level 2 as they have no impact on the actual product.

- Sighted Supplier evaluation form dated October 2023 (initial evaluation).
  Controls include a quality agreement and ISO certification.
  - Sighted Supplier Quality Agreement for TSS Sensitive Freight dated October 2023.
  - Sighted ISO9001 Certificate Exp 14/11/2027

TR Calibrations.

Considered as a risk level 2 vendor.

- Sighted Supplier evaluation form dated August 2023 (initial evaluation).
  Controls imposed include ISO 17025 certification, survey, and quality agreements.
  - Sighted Supplier Quality Agreement for TR Calibration dated October 2023.
  - Sighted https://nata.com.au/accredited-organisation/tr-calibration-sydney-facility-116-109/?highlight=tR%20calibration
  - Sighted documentation package containing NATA and ISO 9001 Certification.

Re-evaluation processes are being developed as part of the new procedure. As such, no re-evaluations have been conducted at this time.

A project plan has been developed for the introduction of the new procedure and subsequent works.

- Sighted Rationale for Non-compliance to E09 & Q07-WI-0000012 for Steris Australia and Steris New Zealand FY25.
  The plan shows a commitment to the implementation of the new E09 within the business, that was not considered as part of the takeover of the business.
  The phased approach also indicates the need to retrospectively manage existing suppliers with the adopted process.

A procedure is (local) is put I place for the internal sales of outputs.

- Sighted WI-02481 Rev A, Creating an Intercompany Stock Order
- Sighted WI-02484 Rev A, Receipting in a Purchase Order

Purchasing is split into 3 categories being,

- Consumables
- Capitals
- Services parts

The categories include their relationship with the outsourced processes (3PL, Calibration suppliers etc.).

With respect to capitol side of the business, the majority of the orders are “made to order”.

When the PO is received from the sales, this is converted to a sales order, and then procurements places the order with the manufacturer (head office).

An internal sales order is then placed with the manufacturer.

- Sales Order 17813007 for the sales and installation of Serial 13144422 Advantage Plus
  Product 12510003 Requisition Number 1170 (ISO) 138372
  Information provided on the ISO provided to the vendor includes
  - Item number
  - Quantity
  - Pricing
  - Delivery dates
  - Delivery addresses. (3PL Partner – TSS Melbourne).

Information is provided though the Oracle computer system (owned by the manufacturer). The same system and processes are used for consumables and spare parts ordered through the manufacturers.

Verification of purchased goods is conducted at the 3PL vendor. Instructions are provided to the vendor.

- SOP-0358 Rev D, Storage Handing and Distribution
  Examples of requirements include
  - Temperature, humidity etc are to be monitored as required.
  - Reporting of damaged or dropped materials to area supervisors
  - NCP are to be identified, quarantined and processed as per their internal non-conforming procedures.

Typically, this is a reflection of the quantity, damage, verification of any batch/serial numbers and information provided on the packing list.

- Sighted Packing List 138371 (consolidated with ISO 138372).
  Evidence of acceptance of the goods is maintained through the vendor's Warehouse Management System. STERIS has access to these records.
  Internally, the STERIS staff also receipt the order into the Oracle system, once they have verified the acceptance with the vendor.
- Sighted TSS WMS, showing product history and acceptance of the goods.

The following example is of consumable products managed through the NZ part of the business.

- Sighted ISO 171055 used to replenish local stock in the 3PL provider.

The product was verified at incoming at the 3PL provider.

- Sighted Shipping documentation and packing list
  - Packing list 425241973 for ISO 171055
  - Verification of the order is marinated through the 3PL WMS (MainChain).

MOQ's are maintained and S&OP meetings provide the planning article to ensure that minimum requirements are met.

Cycle counts, demanded by finance and imposed to the 3PL, are maintained and communicated to STERIS.

Cycle counts are mandated to be conducted monthly from each 3PL vendor.

- Sighted Cycle Count IRA STERIS template (January and February 2025).

Discrepancies between the WMS system, the STERIS systems, as well as physical counts are reported.

Commentary is provided by the 3PL as well as the STERIS staff. Further investigations may be requested by STERIS to the vendor.

Thresholds for investigations are set by finance teams.

In the event of issues with receipted goods, the manufacturer is to raise internal non-conformance procedures.

This is exemplified with leaking Rapicide product discovered at a 3PL provider. The product was quarantined and managed in accordance with the MDSD.

Internally a CAPA was raised for this (refer to Check section of this report).

Verification of auditing on all shifts

Name of production process	Executive shift	Audit cycle					
		Initial- / Re-certification audit	1. Surveillance audit	2. Surveillance audit	3. Surveillance audit	4. Surveillance audit	5. Surveillance audit
Sales	1, 2, 3	X					
Installation	1, 2, 3	X					
Service	1, 2, 3	X					
Warehouse	1, 2, 3	X					

This example shows the following shift times:
- Shift 1 (09:00 – 17:00 o'clock)

2.5 CHECK: Results and analysis

Monitoring of the service/installation processes are conducted through the following articles.

a)Internal audits (refer Check discussions)

b)Trending in complaints conducted as part of the management review meetings (Check sections of this report)

c)Service managers and team leaders will verify that the installation/service records are completed on a monthly basis.

d)Training of the technical services team (refer competence discussions.).

The outcome of the above is fed into the service delivery objectives as well as customer satisfaction.

Other monitoring tasks are established as objectives and performance indicators.

1.Support STERIS ANZ ISO 9001 Certification, Internal and External Audit.
As monitored through several improvement initiatives introduced into the organisation.

2.Minimize the nonconformities from 3 to 2.

3.Maintain an average number of calendar months (i.e., 6 months) that meets DIFOT benchmark, e.g. 95%
Sources of data come from 3PL partners who present DIFOT data on a monthly basis.
The data is then collated by the supply chain team for input into the management review process.
- oSighted KPI Report from Hellmann dated November 2024.
- oB01-TM-001_1_ANZ Management Review_Nov24

4.Achieve 70% of timely preventive maintenance tasks for Technical Services.
Data is output from the computer program SIEBEL and fed into management review. The report is run each month for the Technical Services Director to review the data.
- oSighted B01-TM-001_1_ANZ Management Review_Nov24
- oSighted PM Ontime Report (living document).
  The document shows the on-time completion of the service articles (within the given month of service). The data is shared with the service managers.
  Data from NZ an Australia is considered.
  Action planning is then conducted to correct and understand negative trend

Customer satisfaction.

The output for customer satisfaction is gauged though an ANZ complaints processes.

- •Sighted Q11-001 R4, Complaint Management

Complaints are broken into two categories being

- •Operational Complaints (via NPS)
  The Net Promotor Score is driven by the global teams. Data is fed back to the local teams via a breakdown spreadsheet provided by head office biannually.
  Data is fed into the management review.
  - oSighted APAC NPS Response FY25 June 24-Dec 24. This data is not yet presented within the management review cycle.
  - oSighted B01-TM-001_1_ANZ Management Review_Nov24
- •Product complaints (trended via management review) and driven via WI02455 Rev 1, Steris ANZ Complaints Process

Data is receipted via phone or email etc. then fed into a live Sharepoint Form. From this data is placed into TrackWise via Oracle.

A global procedure is made available for the internal audit programme.

- Sighted Q14-QSE-000001 R2, Internal Audit.

An annual audit schedule is developed by the Global Regulatory department. This also include the plan, relevant to the importance of the processes being audited. A risk assessment is conducted to assist with the audit planning and determination of process relevance.

Auditors are to be independent and suitably qualified and possess the knowledge and skills relevant to the areas being audited.

The last internal audit was conducted by the US internal auditors via remote tools on 20/11/2024

- Sighted IA-01488 Heatherton New Zealand Audit Report dated 20/11/2024
- Sighted AP-00007 Audit Plan (TrackWise record).
- Sighted Program File (TrackWise) document for IA-01488
  - Showing the criterion as the quality manual as well as the requirements of ISO 9001:2015
- Sighted Internal Auditor training records and certificates including STERIS Internal Auditor Training and Competence assessment

Audit findings shall be remediated and managed via TrackWise.

Response timelines are indicated within the relevant Work Instruction

- Sighted Q14-WI000004 R9 Internal Audit

  The work instruction indicates that a maximum response time of 30 business days is required for responses.

Findings are graded in accordance CWI14-001-01 R8, Internal Audit where gradings 2/3 are minor, 4/5 are major. Criterion is applied and defined to each grading.

In the last audit report 1 finding was issued.

AF-01712 - Refer to ACT discussions for further information.

Management reviews are conducted in accordance with global procedure.

- Sighted Q02-001 R9, Management Review

Management reviews are conducted twice annually. For the intent of ISO 9001, as this is a recently adopted standard, only one management review has been conducted.

The last management review was conducted on November 2024.

- Sighted B01-TM-001_1_ANZ Management Review_Nov24

Agenda items to the system include

- Resource needs, discussed within the meeting minutes, for additional headcount within the quality department.
- Risk and opportunities are not directly seen within the management review data as the risk register is only newly developed, the 3 lines of risks pertaining to CAPA's are already being discussed as part of the review meetings.
- Performance of suppliers. Coupled with supply chain performance

A change control has been established to provide a local procedure for management review better aligned with the requirements of ISO 9001:2015 as opposed to ISO 13485:2016 (indicated within the global procedures).

- Sighted CHNG-009 Development of Management Review Agenda

Type	Area/Process	Clause
OFI	Management Review	ISO 9001 Cl 9.3.2
Details:	Consider revisiting the management review data once the new process has been implemented.	

Statement of why OFI is not classified as NC	The requirements of the review inputs are seen within the meeting minutes; however, the organisation is developing a local procedure, via CHNG-009, to better align the process with ISO 9001. The current global process is driven around ISO 13485.

Membership to the meeting includes, Managing Director, Departmental Managers, and APAC representatives. These functions are considered top management (refer to leadership discussions.)

- Sighted Attendance Record for B01-TM-001_1_ANZ Management Review_Nov24

Outputs of the management review are manifested in meeting minutes to drive improvements and foster enhancements within the management system.

- Sighted Management Review Meeting Minutes for B01-TM-001_1_ANZ Management Review_Nov24

2.6 ACT: Improvements

Corrective and preventive actions are (primarily) driven through the following procedures.

- Q12-001 R2, Nonconforming Product reserved for one-time issues.
- Q13-001 R2, Corrective and Preventive Action reserved for systemic issues within the management system.

Inputs into the CAPA process include but are not limited to, complaints, process/product NC's, Management Review, Audit Reports, Continuous Improvement Plan.

CAPA's are required to be reviewed on the back of risk assessments. Root cause, action planning and plan approval are required. Plan approval is to be independently completed of the CAPA owner function.

Effectiveness and verification/validation of effectiveness are gauged on a case-by-case basis.

The CAPA is to remain open until the verification/validation of effective closure is seen.

The following CAPA was reviewed

CAPA 01039 – Regarding leaking products including customer complaints as well as internally.

Roughly 315 units were found across 2 SKU's.

A risk assessment was documented within CAPA report.

The issue was raised with the R&D team of the BU for rectification.

Containment actions included the application of Tip and Tell indicators as part of cause analysis works.

The CAPA remains open at the cause analysis phase.

In addition to the above, part of the improvement lifecycle includes internal audit findings, driven through TrackWise (software tool) as part of the internal audit procedure (refer to internal audit discussions.

The following record was sighted within the TrackWise computer tool.

AF-01712 - The process for training is not entirely effective with the following details.

1.) Missing Service Controls training per Q08-QSE-000008 and Customer Management per Q11-QSE-000002 for

Service - Field Service Technicians. Heatherton and New Zealand facility positions are not following the minimum Quality training requirements per Q03-LS-000001, Training Matrix, Version 6.

2.) Training records were requested per the training plan requirements of TP-00602_TS for the following employees but was not received:

- ••Mantoufeh, Mr. Naim
- ••Dermitzakis, Mr. Michael
- ••Russell, Mrs. Alana
- ••Main, Campbell
- ••Chan, David
- ••Hope, Mr. Chris

3.) QMS and Technical training records were requested for the below recent new hire employees but not received:

- ••Joel Dickson
- ••Tim Messenger
- ••Benjamin Mossman

The cause was determined to be lack of correct tools to generate the report in Propel (software tool). As such, the evidence could not be presented to the auditor.

Containment actions included IT department to correct the Propel Report and ensure it's functional. Evidence of the corrected report was supplied to the auditor

Corrective actions were to ensure that the training report can be generated for an effectiveness period until May 2025.

2.7 Additional strengths and improvement potential

Listing of strengths, as presented in the closing meeting
Excellent procedural controls with respect service and installation instructions and forms.

Listing of improvement potential, as presented in the closing meeting
as identified in the closing meeting and the body of this report.

3 Audit results

ISO 9001:2015

Current scope of registration:	Distribution, installation and servicing of active devices for disinfection, sterilization, endoscopic & surgical procedures, drying chamber and consumables
The top-level Management System manual and related management system documentation were reviewed and found to conform to all applicable standard requirements for documentation.	Current revision of manual: 9 ☒ Yes ☐ No Remarks: None
The management system is effective and fulfils the requirements:	☐ Yes ☒ Only partly – see corrective action plans ☐ No – see corrective action plans
Number of findings:	Major nonconformities: 0 Minor nonconformities: 2
On site verification of nonconformities needed via follow-up / special audits:	☐ Yes ☒ No

4 Order and audit process data

4.1 Order data

Name of the company:	STERIS AUSTRALIA PTY LTD
Main address:	9 Arco Lane, Heatherton, VIC 3202 Australia
Ref. No.:	50000373
Date of audit:	17 Fab 2025 to 21 Feb 202521-Feb-2029
Total number of person-days (PD):	3.5 (AUS 3.0 days + NZ 0.5 day)
Date of system analysis: (if applicable)	21 Feb 202521-Feb-2029
SIC / IAF / EA / NACE Code: (Primary)	19.2
SIC / IAF / EA / NACE: (Secondary, as applicable)	31.1
Non-applicable requirements	☒-Cl 8.3 Desgin and Development *(please specify)*
Number of employees currently covered by registration at main site:	AUS 140 - EFT 85 NZ 10 - EFT 5

4.2 Management and contact persons

Top Manager at site:	Peter Pergaminos
Telephone:	1300 211 422
E-mail:	NA
Management Representative:	Arshjot Ramana
Telephone:	0414 590 965
E-mail:	Arshjot_ramana@steris.com
Audit Team Leader:	Marko Miklic
Telephone:	+61 418 122 641
E-mail:	Marko@distinctengineering.com.au
Customer Service of DQS:	Ms. Tilda Renton
Telephone:	tilda@dqs.global
E-mail:	+61 3 8804 4940

4.3 Audit data

Audited sites and sampling basis

Site: Head Office – 9 Arco Lane, Heatherton VIC Ref. No.: 50000373 Shifts: 1

Main business/processes at location, please specify: Sales, installation, servicing, warehousing (outsourced)

	Actual	Number interviewed	In %
Executive managers	11	3	27
Other employees	129	10	8
Total	140	13	9

Additional Sites:

The following additional sites is currently covered by this certification:

Site: New Zealand Office (Steris New Zealand Ltd) Ref. No.: 50000690 Shifts: 1
4th Floor, Smith & Caughey Building, 253 Queen Street Auckland, New Zealand

Main business/processes at location, please specify: Sales, installation, servicing, warehousing (outsourced)

	Actual	Number interviewed	In %
Executive managers	1	1	100
Other employees	9	1	11
Total	10	2	20

Date Agenda sent to Client: 4 Feb 2025 (v2), Initial 14 Jan 2025

Audit sequence: ☒ The Audit Plan was maintained

☐ The Audit Plan was altered as follows:

Closing meeting:
A closing meeting was performed with the organization's management. Audit results were presented, explained and, where necessary, discussed. Findings and corrective action plans were agreed upon with the respective managers, as necessary.

5 Next steps

5.1 Activities of the customer

Corrective actions:

☐ Corrective actions not necessary

☒ Corrective actions will be implemented and reviewed for effectiveness as agreed by the next audit.

Opportunities for Improvement: Identified improvement potential will be evaluated internally and incorporated into the continual improvement process if deemed beneficial.

Nonconformities, identified during an audit, shall be closed with evidence of effectiveness within defined time lines. Otherwise, certificates may be suspended or withdrawn.

5.2 Activities of

Type of next audit:

☒ Surveillance audit

☐ Recertification audit

☐ Special audit

Next audit data:
(non-binding estimate of person days)

Planned date for next audit: February 2026
(week or month, if appropriate)

For 2 person-day(s)

By 1 auditor(s)

Main emphasis will be on the following subjects: Development of risks and monitoring activities.

Customer requests:

☐ Information on

☐ Quotation for

☐ Telephone call from Customer Service Representative

Additional remarks: None

5.3 Identified need for change

Basic data changed? ☐ Yes ☒ No

6 Additional documents

☒ Findings with corrective action plan
(the customer at the end of the audit supplied by the Auditor) — Number: 2

For internal use only:

☐ Basic data — Number:

☐ Basic data –standards [if appropriate] — Number:

☐ Auditor notes / Audit record

☐ List(s) of participants - closing meeting

☐ Reviewed draft certificate(s) [if appropriate] — Number:

☐ Others

Report prepared on 21 Feb 2025

Lead Auditor Marko MiklicMarko Miklic
Standard ISO 9001:2015

25/02/2025
Date

Technical review on behalf of DQS

Confidentiality

DQS maintains ownership of this report. The content of this report and all information received in relation to the audit and certification of the audited organization will be treated confidential and not disclosed to third parties. For exceptions e.g. disclosure to accreditation body refer to DQS Certification and Assessment Regulations.
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