

General information regarding elements of the certification process is described below. A degree of flexibility and options in the certification process are available so please feel free to contact us to discuss how we can better serve your organization.

SAI Global Full Service Team

Upon selection of SAI Global as your Registrar and submission of the signed Application for Certification, SAI Global will assign your dedicated service team.

Your service team will be selected to suit your specific industry and will consist of an Account Manager, a Regional Account Representative, a Lead Auditor and other team members as needed to support your certification. The roles of each member of your service team are as follows: your Account Manager will manage the business relationship, including contract negotiation and changes to your certification requirements; your Regional Account Representative will manage the back office processes including scheduling and customer service related to certificates and invoicing; your Lead Auditor will manage the delivery relationship. As your primary contact with SAI Global, the Lead Auditor assigned provides you with ongoing industry developments and interpretations and ensures coordination of all audit-related activities for your company. If additional audit team members are required, they are selected from our experienced auditor base. Your audits will be consistent in approach, technically sound and relevant to your business needs. You can not object to the composition of the audit team as described in ISO/IEC 17021:2015 clause 9.2.3.5. You can utilize the appeals process to notify SAI Global of any concerns related to the audit team composition. (See IMDRF/MDSAP WG/N3 Final:2016 9.1)

Introductory Visit – (Optional) (formally referred to as a Preliminary Assessment)

An introductory visit is an on-site assessment conducted prior to the Stage 1 Certification Audit. The introductory visit allows for the identification of any major implementation issues and feedback regarding your implementation readiness. We recommend that your preliminary assessment be scheduled at least 30 days prior to the Stage 1 Audit. Findings from any audit, (“mock audits,” “gap audits,” or “pre-assessment audits” outside of the scope of Stage 1/Stage 2 audits), shall be documented and taken into consideration when grading nonconformities identified at a subsequent regulatory audit.

Certification Audit

The goal of the certification audit is to assess the effective implementation of your management system to the requirements of the standard and your management system documentation. The audit is conducted in two Stages.

The Stage 1 audit is generally conducted on site and consists of a documentation review and establishes the audit scope and audit plan.

The Stage 2 audit is conducted on site and consists of a review to ensure that the management system has been fully implemented and is in conformance to the requirements of the standard or normative document.

All audit activities are mutually planned with your assigned Auditor prior to the audit. An audit plan is provided detailing the scope and objectives of both the Stage 1 and Stage 2 audit, the audit team members, the processes to be audited and the timelines. While onsite your audit team will work to verify that the management system meets the requirements of the standard and your system documentation by assessing objective evidence. At the conclusion of the onsite audit, you will be immediately informed of the results. A formal audit report will be issued after the audit. The report includes information relative to positive aspects of the system and system non-conformances.

Please note that if you request the option of having the Stage 1 and Stage 2 Audits conducted back to back a potential risk is present in that unacceptable Stage 1 audit results may require the cancellation of the Stage 2 audit with the application of cancellation fees as outlined in the terms and conditions.

Certificate Issuance

Upon successful completion of the certification process (including resolution of non-conformances if applicable), your Team Leader compiles a Certification Package for review by our Certification Team. Upon completion of the review, the Certification Team prepares and forwards your Certificate of Registration. Your certificate will include details such as: legal company name, site address, standard, scope of certification, the initial certification date and the expiry date.

The official certificate is forwarded, along with a link to our marketing website. The Marketing tools will provide you with useful ideas on how to capitalize on your ISO certification, provide you with the official 'SAI Global registered mark' artwork and the guidelines of use. Your successful certification will also be published in our online Directory of Registered Companies, at www.saiglobal.com.

Surveillance Audits

Surveillance audits are periodic audits of your management system. The purpose of surveillance audits is to ensure the management system is being maintained during the effective period of certification. To provide you with as much flexibility as possible, SAI Global offers two surveillance frequency options: Annual and Semi-annual.

- Semi-Annual audits are conducted every six months. This option offers more frequent interaction with your audit team, to ensure your management system is working efficiently and to facilitate the rate of continuous improvement.
- Annual audits are conducted every twelve months, as a minimum.

Re-certification audit

Re-certification Audits are scheduled before 3-year mark, usually 3 months before the certificate expiry date.

The purpose is to ensure:

- The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of the Certification
- Client demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance.
- Whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives

Supplemental scheme requirements

In addition to the requirements in Section 4 – Conditions of Certification, the following additional sector-specific requirements apply:

SAI Global is obliged to provide to the various applicable Regulatory Authorities with a copy of the Auditing Organization team's reports, documents and records related to medical device audits of the Client's Quality System. Regulatory Authorities can share all documents and records related to medical device audits with other Regulatory Authorities that have formal established confidentiality agreements between governments which covers provisions for protecting proprietary information and trade secret information(See IMDRF/MDSAP WG/N3 Final:2016 clause 5.1.5).



These applicable Regulatory Authorities may also, at its discretion, observe a registration or surveillance audit of the Client conducted by accredited Auditing Organizations such as SAI Global. This could include allowing personnel from the Regulatory Authority(s) access to records and documents pertaining to the manufacturer that is relevant to the audit and decision making process upon request. (See IMDRF/MDSAP WG/N3 Final:2016 clause 5.1.4).

SAI Global also reserves the right to visit the Client if deemed necessary to determine the Client's control over the Quality System. Additionally, with regard to short notice audits identified in clause 6.2, it is understood that Regulatory Authorities themselves may perform special audits, including unannounced audits, anytime it deems necessary and within the purview of its jurisdiction. Within this authority, upon request by the recognizing Regulatory Authority(s), SAI Global (as the Auditing Organization) can perform a special audit of under the direction of the recognizing Regulatory Authority(s) requesting the special audit. An unannounced audit can occur following any audit that results in: a) one or more nonconformity(s) graded as a "5"; or, b) more than two nonconformities graded as a "4", based on GHTF/SG3/N19:2016 to grade the nonconformities. Unannounced audits on premises of the manufacturer or of his contracted critical suppliers is addressed in SAI Global's contractual arrangements; both between the manufacturer and the critical supplier, and between the auditing organization and the manufacturers. (See IMDRF/MDSAP WG/N3 Final:2016 clause 9.5).

MDSAP standards should be consulted for definitions that are particular to this supplemental scheme and parties are bound by future revisions to these MDSAP standards.