ABOUT SGS

ABOUT MDSAP

MDSAP AUDIT MODEL

DEMONSTRATE REGULATORY COMPLIANCE
WITH A SINGLE AUDIT

MEDICAL DEVICE SINGLE AUDIT PROGRAMME (MDSAP)

SGS

ABOUT SGS

LEADERSHIP AND INNOVATION SINCE 1878

90,000
EMPLOYEES

2,000
OFFICES & LABORATORIES

- 1,150 offices & laboratories; 36,900 employees in Europe, Africa & Middle East
- 450 offices & laboratories; 21,600 employees in Americas
- 400 offices & laboratories; 31,500 employees in Asia Pacific

1878

SGS transformed grain trading in Europe by offering innovative agricultural inspection services.

1913

Become leader in grain inspection (21 million tons).

1919

Adopted the name it carries today, Société Générale de Surveillance.

1928

The company had grown internationally, with offices and affiliates in 21 countries around the world.

1946

Begun inspection of European imports.

1950

80% of the company's revenue still came from its core Agricultural Services business.

1980

The company now had 113 offices, 57 laboratories and 9,500 employees working in over 140 countries around the world.

1981

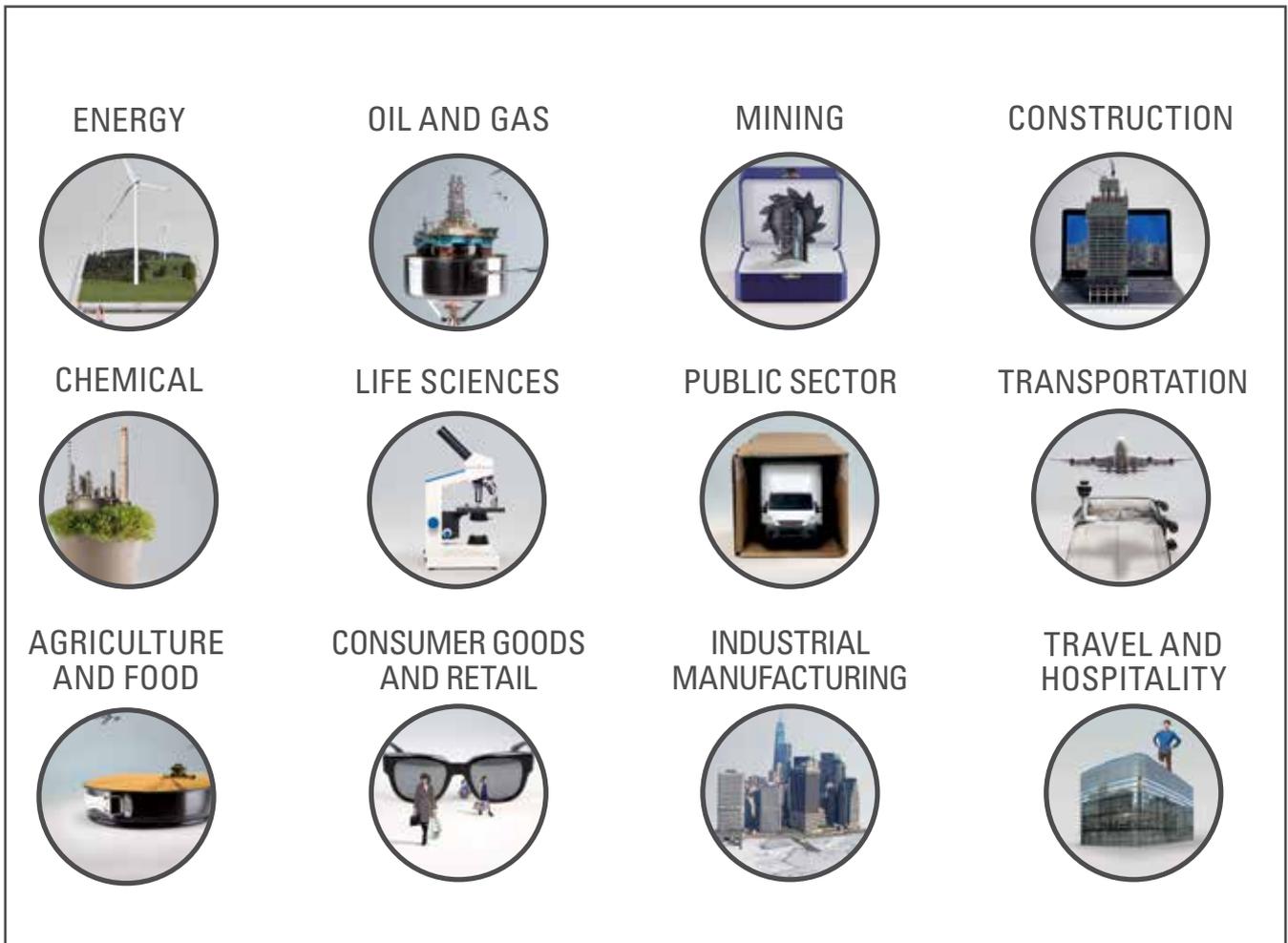SGS was listed on the Swiss Stock Exchange.

SINCE 2000

Listed more than 160 acquisitions.

TODAY

SGS celebrates more than 140 years in the business.

OPERATING ACROSS A WIDE VARIETY OF INDUSTRY SECTORS

ENERGY

OIL AND GAS

MINING

CONSTRUCTION

CHEMICAL

LIFE SCIENCES

PUBLIC SECTOR

TRANSPORTATION

AGRICULTURE AND FOOD

CONSUMER GOODS AND RETAIL

INDUSTRIAL MANUFACTURING

TRAVEL AND HOSPITALITY

SGS BUSINESS BENEFITS

- Deliver innovative solutions and services that transform our customers' operations.
- Enhance processes, systems and skills.
- Offer solutions and services fundamental to ongoing success and sustained growth.
- Enable continuous improvement.
- Improve our customers' operations, meet their stakeholder requirements and manage their sustainability and social responsibility needs.
- Transform our customers' value chains.

200,000
CUSTOMERS

165,000
ISSUED CERTIFICATES

ABOUT MDSAP

The Medical Device Single Audit Programme (MDSAP) has been developed to allow recognised auditing organisations to conduct a single audit of a medical device manufacturer that will be accepted by all five regulatory authorities participating in the programme:

- Therapeutic Goods Administration of Australia (TGA)
- Brazilian Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada
- United States Food and Drug Administration (US FDA)
- Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)
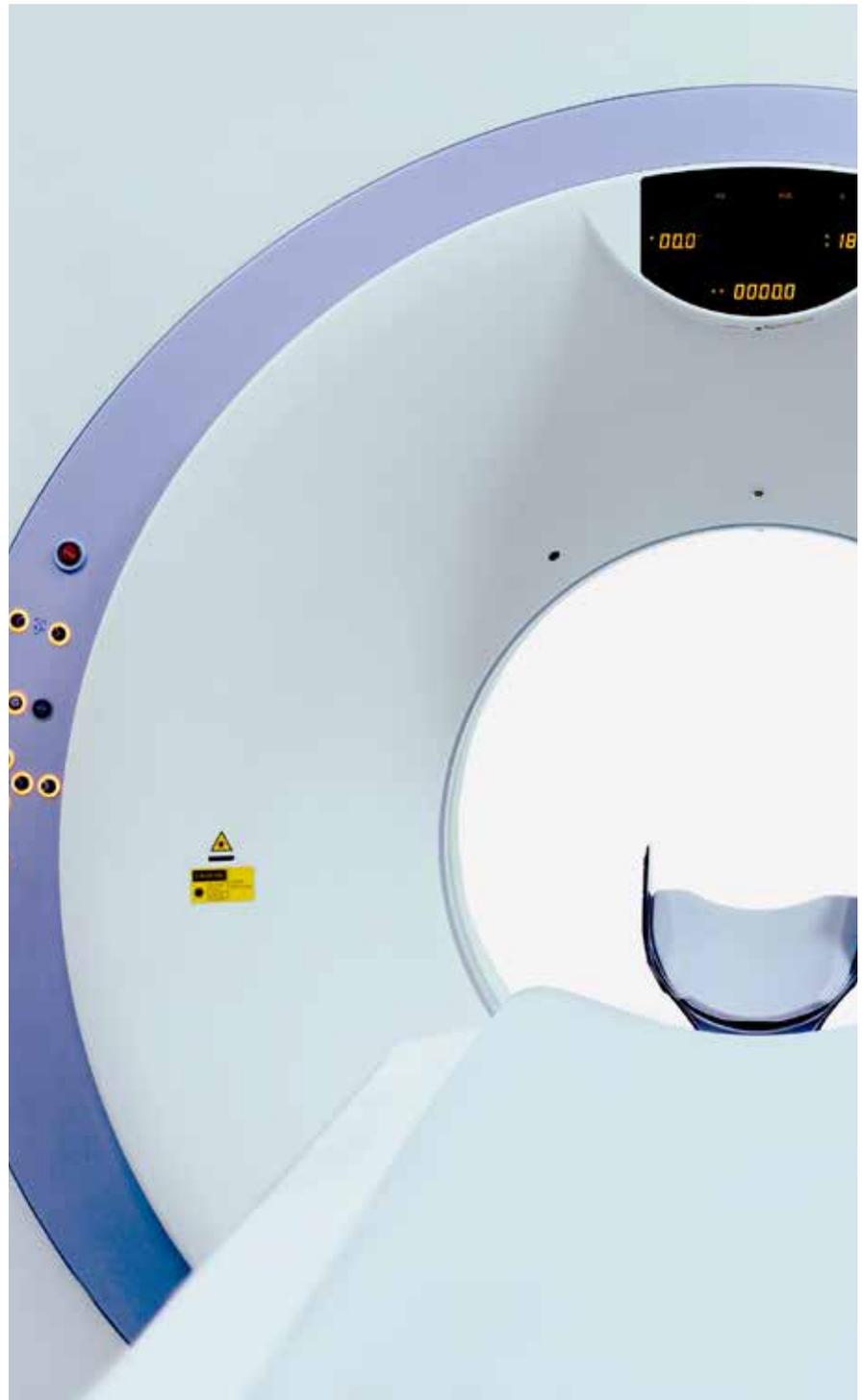
The World Health Organisation (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers.

OBJECTIVES

The mission of the participant regulatory authorities in the MDSAP is to jointly leverage regulatory resources to manage an effective, efficient and sustainable single audit programme focused on the oversight of medical device manufacturers.

Their objectives are:

- To operate a single audit programme that provides confidence in programme outcomes
- To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems – minimising regulatory and industry burdens without compromising public health
- To promote more efficient and flexible use of regulatory resources through work sharing and mutual acceptance among regulators, while respecting the sovereignty of each authority
- To leverage, where appropriate, existing conformity assessment structures
- To promote, in the long term, greater alignment of regulatory approaches and technical requirements, based on international standards and best practices
- To promote consistency, predictability and transparency of regulatory programmes

TIMELINES

The MDSAP pilot was launched on 1 January 2014, starting with a three year pilot that ended 31 December 2016. The operational phase of the programme began on 1 January 2017.

TRANSITION OF CMDCAS TO MDSAP

On 4 December 2015, Health Canada announced that it intended to implement MDSAP as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements of Medical Devices Regulations.

MDSAP will replace the current Canadian Medical Devices Conformity Assessment System (CMDCAS) programme, even when a manufacturer intends to sell only in Canada.
The period for transitioning from CMDCAS began on 1 January 2017, after the conclusion of the MDSAP pilot, and will last for two years.

During this two year period, Health Canada will accept certificates issued under both CMDCAS and MDSAP. As of 1 January 2019, all CMDCAS certificates are invalid, and only MDSAP certificates will be accepted.

It is important to note that the programme does not allow the exclusion of any country regulations from the certification scope if products are marketed in that country. A manufacturer may exclude the requirements of a jurisdiction where the organisation does not intend to supply medical devices.

BENEFITS FOR OUR CLIENTS

MDSAP replaces multiple regulatory audits with a single audit covering all the relevant requirements of those regulatory authorities participating in the MDSAP. By participating in the MDSAP programme you can:

- Gain access to multiple markets with a single audit
- Minimise business disruption, while optimising time and resources
- Ensure complete coverage of the requirements of all five participating regulatory authorities
- Have routine audits scheduled directly with the auditing organisation

Importantly, the programme does not add any new requirements to existing requirements of ISO 13485 standard, or

to the medical device regulations of the participating authorities.

If you are interested in participating in the programme, please contact your local SGS office.

WAYS REGULATORY AUTHORITIES CAN UTILISE THE SINGLE AUDIT PROGRAMME AND THE RESULTING REPORT/CERTIFICATION

Australia: The TGA will use the MDSAP audit report as part of the evidence that is assessed for compliance with medical device market authorisation requirements, unless the medical device is otherwise excluded or exempted from these requirements, or if current policies restrict the use of MDSAP audit reports.

Brazil: ANVISA will utilise the outcomes of the programme, including reports, to provide input on ANVISA's pre-market and post-market assessment procedures, including, where applicable, key information expected to support regulatory technical evaluation on these issues.

Canada: HC will use the MDSAP audit as part of its CMDCAS certification programme. HC will implement the MDSAP as the mechanism for achieving regulatory compliance for quality management system requirements in Canada.

United States: the FCS Centre for Devices and Radiological Health will accept MDSAP audit reports as a substitute for FDA routine inspections. Inspections conducted for cause or compliance follow-up will not be affected by this programme. The MDSAP programme will not apply to any necessary pre-approval or post approval inspections for premarket approval (PMA) applications or to decisions under section 513(f)(5) of the act concerning the classification of a device (21 U.S.C. 360c(f)(5)).

Japan: The MHLW and PMDA will use MDSAP audit reports in premarket and periodic post market audits, which will lead to the reduction of the documentation required for these audits.

MDSAP AUDIT MODEL

The MDSAP audit process provides complete coverage of the requirements of ISO 13485 (Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes), the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169), the Quality System Regulation (21 CFR Part 820) and other specific requirements of medical device regulatory authorities participating in the MDSAP programme, including registration, licensing, technical documentation review and adverse event reporting.

Medical device manufacturers are audited according to the scope declared in their application for certification services. Based on the countries where the manufacturer sells (or intends to sell) or has devices registered, the regulatory requirements applicable to that manufacturer will be determined.

The MDSAP Audit Model and Companion Document are used to make that determination. These documents reference the applicable ISO 13485 clause(s), and the regulatory requirements of each of the participating regulatory authorities.

The Audit Model MDSAP AU P0002 and Companion Document MDSAP AU G0002.1 have been recently amended to reflect changes from ISO 13485:2003 to ISO 13485:2016.

During the transition period for ISO 13485 (from the 2003 edition to the 2016 version) two versions of the Audit Model and Companion Document will be available, and accepted under MDSAP. Organisations that have transitioned from ISO 13485:2003 to the 2016 edition and applying for MDSAP certification will be audited against the most recent version of the MDSAP Audit Model and Companion Document

AUDIT SEQUENCE

The MDSAP audit sequence follows a process approach and has four primary processes:
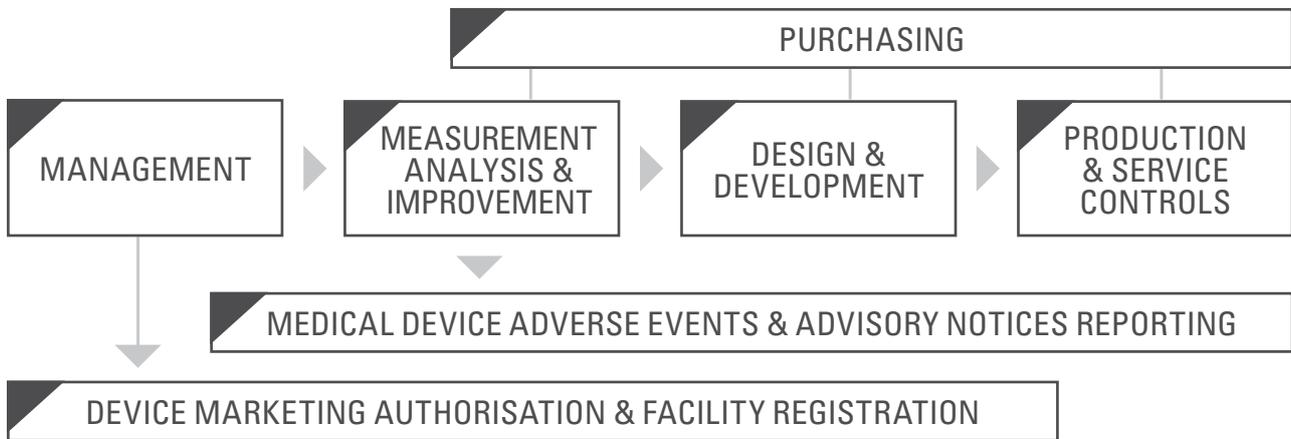
1. Management
2. Measurement, Analysis and Improvement
3. Design and Development
4. Production and Service Controls

And three supporting processes:

1. Purchasing
2. Device Marketing Authorisation and Facility Registration
3. Medical Device Adverse Events and Advisory Notices Reporting

FIGURE 1

The flowchart shown in Figure 1, documents the MDSAP audit sequence and interrelationships. The MDSAP audit model was designed for the audit of the primary MDSAP processes in the following sequence: Management; Measurement, Analysis and Improvement; Design and Development; and Production and Service Controls.

The Purchasing process (5) may be reviewed in conjunction with the Measurement, Analysis and Improvement process, the Design and Development process, and the Production and Service Controls process.

MDSAP AUDIT CYCLE

The MDSAP is based on a three year audit cycle. The Initial Audit, also referred to as the "Initial Certification Audit" is a complete audit of a medical device manufacturer's quality management system (QMS). It consists of a Stage 1 Audit and a Stage 2 Audit. The initial audit is followed by a partial Surveillance Audit in each of the following two years and a complete Re-audit, also referred to as a "Recertification Audit" in the third year.

Special Audits, Audits Conducted by Regulatory Authorities, and Unannounced Audits are potential extraordinary audits that may occur at any time within the audit cycle.

WHY SGS?

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 90,000 employees, SGS operates a network of over 2,000 offices and laboratories around the world.

We are constantly looking beyond customers' and society's expectations in order to deliver market leading services wherever they are needed. We have a history of undertaking and successfully executing large-scale, complex international projects. With a presence in every single region around the globe, our people speak the language and understand the culture of the local market, and operate globally in a consistent, reliable and effective manner.

RELATED LINKS

Full details on the MDSAP and answers to frequently asked questions are available on:

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

Other links:

MDSAP guidance documents:

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm

To learn how SGS can help your organisation with MDSAP, visit www.sgs.com/mdsap or contact your local SGS office or email us at medicaldevices@sgs.com

WWW.SGS.COM

WHEN YOU NEED TO BE SURE

SGS