



Global Market Access through
Medical Device Single Audit Program (MDSAP)

Medical Device Single Audit Program (MDSAP) allows a single audit of a medical device manufacturers QMS which satisfies the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations (AO), such as BSI, authorized by the participating Regulatory Authorities (RA) to audit under MDSAP requirements.

MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.

A BSI MDSAP Audit can also be combined with assessment for CE and ISO 13485.

MDSAP audits can be performed by a recognized MDSAP Auditing Organisations (AO), such as BSI. BSI have been active through the MDSAP pilot phase and have now received significant numbers of applications for MDSAP, predominantly from world leading medical device manufacturers. BSI has performed over 200 MDSAP audits worldwide and issued a significant number of global sites with MDSAP certifications and we are currently processing many more.

Which Geographies and Regulatory Authorities are included in MDSAP?

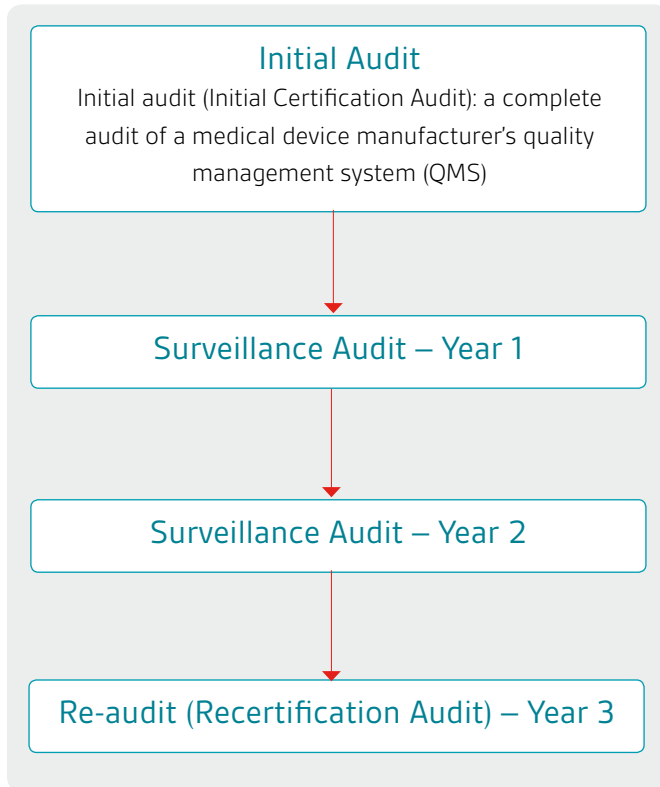
MDSAP should be considered for companies based globally, if they wish to export products into the countries participating, as described below.

The five RA's involved with MDSAP pilot have made the following statements on how they intend to utilize MDSAP reports:

- **Australia:** [The Therapeutics Goods Administration](#) TGA uses an MDSAP audit report as part of the evidence that it assessed for compliance with medical device market authorization requirements. Unless the medical device is otherwise excluded or exempt from these requirements or if current policies restrict the use of MDSAP audit reports.
- **Brazil:** [The Brazilian National Health Surveillance Agency](#) ANVISA utilizes the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post-market assessment procedures. Providing, when applicable, key information that is expected to support regulatory technical evaluation on these issues.
- **Canada:** [Health Canada](#) HC have confirmed the requirement for medical device manufacturers to transition from CMDCAS to MDSAP to continue to place devices into Canada. From 1st January 2019 Health Canada (HC) will ONLY accept MDSAP for manufacturers who market their devices in Canada. Therefore, manufacturers wishing to continue to place product on the market in Canada as of 2019, need to have MDSAP Certification issued by an AO in place before that date.
- **United States:** [U.S. Food and Drug Administration's Center for Devices and Radiological Health](#) FDA will accept the MDSAP audit reports as a substitute for FDA routine inspections. Inspections conducted "For Cause" or "Compliance Follow-up" by FDA will not be affected by this program. Moreover, the MDSAP program would not apply to any necessary pre-approval or post-approval inspections for Pre-Market Approval (PMA) applications or to decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.
- **Japan:** [The Ministry of Health, Labour and Welfare](#) (MHLW) and [Pharmaceutical and Medical Devices Agency](#) (PMDA) will utilize these audit reports in both pre-market and periodical post-market audit under regulations in Japan.

Medical Device Single Audit Program process:

MDSAP is based on a three year audit cycle.



What are the benefits of MDSAP

A Single Audit by Auditing Organizations would:

- minimize medical device manufacturer disruptions due to multiple regulatory audits
- provide predictable audit schedules (agenda with opening and completion dates)
- benefit patient health and patient access with ease of entry to multiple markets
- leverage regulatory resources
- incorporate ISO 13485 assessment requirements, including Australia, Brazil, Canada, Japan and US
- reduction in time and resource dealing with findings from multiple audits
- reduction in the cost of audits in comparison to independent audits
- improved transparencies in the industry.

Where can I find more information on MDSAP to allow me to make the best decision?

- BSI has a dedicated website for your [MDSAP Transition](#)
- BSI Training Course: [Medical Device Single Audit Program \(MDSAP\): Fundamentals and Readiness](#).
- Read the excellent information available free online through the [FDA website](#)

BSI and MDSAP: Our commitment to excellence

BSI is a fully recognized AO. We fully supported the MDSAP pilot and have been conducting audits since September 2014. We've experienced increased interest and applications by manufacturers during 2015, 2016 and 2017. Feedback about the benefits of MDSAP has been overwhelmingly positive.

BSI understands the specific challenges medical device manufacturers face and the importance of bringing innovative yet safe products to global markets. Ensuring the predictability and transparency of regulatory clearance is key to maintaining a competitive edge.

We demonstrate this commitment through:

- Over 100 MDSAP assessors worldwide
- Over 240 QMS ISO 13485 assessors globally
- Over 2,050 years' medical device product and regulatory experience
- Internal Product Experts and Auditors
- Direct access to your team of technical specialists

How do I apply for MDSAP?

For clients holding ISO 13485 and/or CMDCAS, BSI can roll the MDSAP audit into the existing certification cycle.

Contact us for more information on how to apply for MDSAP.

Call BSI today: **+44 345 080 9000**
or visit: **bsigroup.com/MDSAP**

Note: For current clients, we can start the audit in the current visit cycle, ie, surveillance or recertification. BSI can discuss with you the available options depending on your business needs.

Special audits, audits conducted by Regulatory Authorities, and unannounced audits are extraordinary audits that may occur at any time within the audit cycle.

Your resource for excellence

Talk to BSI

- We have 4,000 colleagues globally
- Offices in 30 countries around the world
- Over 81,000 clients operating in 180 countries
- Together our clients account for 75% of the FTSE 100, 51% of the Fortune 500 and 68% of the Nikkei listed companies
- We are one of the world's largest independent certification bodies for management systems, with over 121,000 registered sites across the globe.

Additional services

Medical device newsletter service – Keep updated on what's happening in the industry and changes in regulatory and quality requirements. You can take advantage of this free service by signing up on our website.

Informative webinars – Hear regular updates from our experts on key topics; listen live or listen back.

Comprehensive white papers – Our technical specialists collaborate with external experts to bring you the latest views and understanding on complex regulatory issues. Download your complimentary copies now.

Medical device guidance documents – Our online guidance documents provide assistance in understanding the regulatory requirements for medical devices.

Standards – BSI British Standards delivers leading-edge best practice solutions through the development and publication of more than 37,000 standards and related products.

Your resource in worldwide compliance: Call BSI today on +44 345 080 9000 or visit bsigroup.com/medical – to start your journey.



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