



Image: ©Sergey Nivens/fotolia

# Medical Device Single Audit Program (MDSAP)

“The MDSAP is intended to allow MDSAP-recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the program.”  
*U.S. Food and Drug Administration (FDA)*

## PROGRAM PARTICIPANTS



Australia



Brazil



Canada



United States



Japan

### Program's Regulatory Authority Council

- Australia's Therapeutic Goods Administration (TGA)
- Brazil's Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada (HC)
- U.S. Food and Drug Administration (FDA)
- Pharmaceuticals and Medical Devices Agency (PMDA)
- Japan's Ministry of Health Labour and Welfare (MHLW)

### Official Observers

- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU)

[www.tuv.com/mdsap](http://www.tuv.com/mdsap)

 **TÜVRheinland**<sup>®</sup>  
Precisely Right.

# Frequently Asked Questions on MDSAP

## 1. WHICH VERSION OF ISO 13485 WILL BE CONSIDERED UNDER THE MDSAP PROGRAM?

The transition period of ISO 13485 is honored by the MDSAP program. Until March 1st, 2019, quality management systems compliant to both ISO 13485:2003 and ISO 13485:2016 versions can participate.

After the transition, only ISO 13485:2016 based QMSs can be certified under MDSAP.

## 2. IS THERE ANY SPECIFIC PREPARATORY STEP TO FACILITATE A SUCCESSFUL MDSAP CERTIFICATION?

MDSAP is a conformity assessment program only, which should pose no new requirements. Therefore, the manufacturers currently distributing products to the markets of the participating countries should already be in compliance with the local regulations.

The Auditing Organization (AO) auditors will use the MDSAP audit model and companion document during the audit. Both of these can be a valuable tool during the preparation and can be downloaded from the [FDA MDSAP website](#) under MDSAP AU P0002.

## 3. FOR LEGAL MANUFACTURERS CURRENTLY CERTIFIED TO ISO 13485:2003 UNDER CMDCAS, WHAT IS THE PROCESS OF TRANSFERRING TO MDSAP?

The MDSAP audit has to be performed as an initial certification performed in two stages.

- **Stage 1:** 1 typical manday to evaluate the preparedness for the certification
- **Stage 2:** 5-5.5 typical mandays on-site Stage 2 certification audit.

## 4. WHAT IS THE EARLIEST DATE FROM WHEN CLIENTS CAN ORDER MDSAP CERTIFICATION/AUDIT?

2017-04-01. After this date, in 2017 and 2018, TÜV Rheinland will only offer CMDCAS audits as an exception (with certificate expiry date of Dec. 31st, 2018) to facilitate a timely transfer and meet Health Canada's transition plan.

An earlier application is recommended to ensure a gapless transition.

## 5. CAN THE MDSAP INITIAL CERTIFICATION AUDIT BE COMBINED WITH AUDITS TO THE OTHER CERTIFICATIONS?

Yes, typically the Stage 2 can be performed as part of a combined audit. However this might not always be practical, the overall audit scope and duration will need to be determined individually, and will likely be increased to allow time to evaluate compliance to other requirements (e.g. EC-Directives).

To have the combined audit at the usual date, it is recommended to request the Stage 1 a month earlier than usual. An MDSAP certification audit resulting in negative recommendation does not necessarily jeopardize the other certifications (unless the nonconformity applies generally to other requirements as well).

## 6. WHAT IS TÜV RHEINLAND'S CURRENT STATUS AS AO?

As of January 1st, 2017, we are an authorized AO under the MDSAP program. [The current status can be confirmed here.](#)

## 7. HOW CAN TÜV RHEINLAND HELP YOU WITH MDSAP?

For legal manufacturers marketing their medical device to at least one of the participant countries, MDSAP certification service is offered (with both the MDSAP certificate listing all on-site audited sites covered by the QMS and audit reports per site as deliverable).

For subcontracted medical device part manufacturers currently subject to GMP inspections (e.g. by the FDA or ANVISA), site-specific MDSAP audit report is offered. Pre-audit is not offered for the MDSAP program.

**TUV RHEINLAND OFFERS INFORMATION ABOUT THE MDSAP (MEDICAL DEVICE SINGLE AUDIT PROGRAM). FOR FURTHER QUESTIONS PLEASE GET IN TOUCH WITH US!**

[ONLINE CONTACT](#)