

Medical Device Single Audit Program (MDSAP) - One audit, five markets

Australia - Brazil - Canada - Japan - USA

The Medical Device Single Audit Program (MDSAP) was developed by the International Medical Devices Regulators Forum (IMDRF) to allow medical device manufacturers to demonstrate that their quality management system meets the regulatory requirements of multiple countries through a single audit.

With MDSAP, manufacturers can more easily achieve and/or maintain marketing authorization for medical devices in Australia, Brazil, Canada, Japan, and the United States.

TÜV NORD is an MDSAP recognized auditing organization experienced in conducting conformity assessment and certification in the field of medical devices. It is also an EU notified body for medical devices and an accredited certification body for medical device management systems (ISO 13485) *. Our global Project Management Team supports you as a central point of contact, ensuring efficient coordination and transparent communication worldwide.

* The corresponding recognition, designation or accreditation is maintained by the respective scheme-responsible TÜV NORD organization.



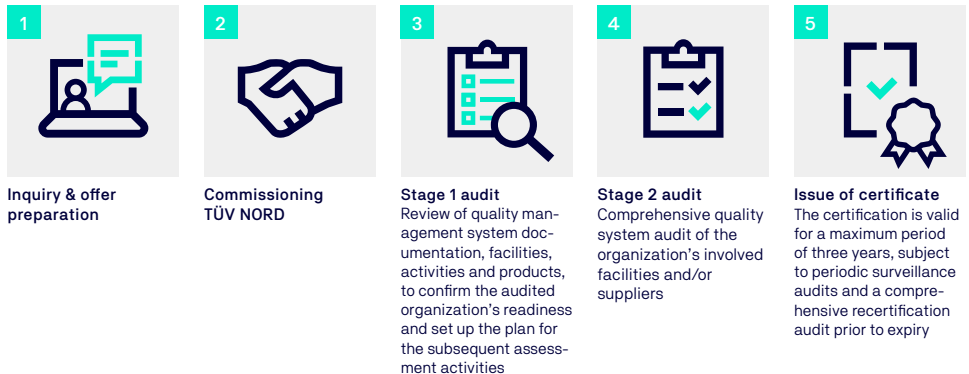
BENEFITS OF MDSAP CERTIFICATION:

- **Demonstrate conformity of the quality management system to ISO 13485 and the regulatory requirements for Australia, Brazil, Canada, Japan and the United States with one audit**
- **Accelerate marketing authorization**
- **Minimize operational disruption**
- **Reduce internal workload**
- **Lower audit time and cost**
- **Create synergies by combining different audit criteria (e.g. MDSAP, MDR, ISO 13485)**

MDSAP MEMBERS:

- **Australia**
Therapeutic Goods Administration (TGA)
- **Brazil**
National Health Surveillance Agency (ANVISA)
- **Canada**
Health Canada (HC)
- **Japan**
Pharmaceuticals and Medical Devices Agency (PMDA), and Ministry of Health, Labor and Welfare (MHLW)
- **United States**
U. S. Food and Drug Administration (FDA)

THE AUDIT PROCESS OF MDSAP CERTIFICATION



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