Medical Device Services

Medical Devices and Quality Management Systems Certification

MEDICAL DEVICE SERVICES

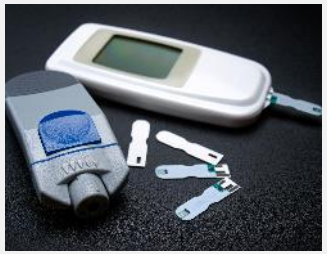
BUSINESS LINES | SERVICES

SERVICES AREAS

ISO 13485 Certification

Medical Device Single Audit Program (MDSAP)

CE Certification MDR



CE Certification IVDD/IVDR

ISO 13485 Certification

ISO 13485 Certification

DEKRA ISO 13485 Certification

- DEKRA's team checks, assesses and, where appropriate, certifies compliance with the ISO 13485 requirements.
- DEKRA is an accredited certification body that provides ISO QMS certification, optionally combined with MDSAP, TCP and/or CE certification.
- DEKRA can include compliance with key standards for the Medical Device industry in the scope of the ISO 13485 certification.

Benefits

- Proof of compliance with the relevant management system guidelines for the development, manufacturing and distribution of medical devices.
- Increased operational efficiency and lower risks.
- Concrete basis to demonstrate a regulatory compliant and quality-focused approach to medical device design, development and manufacturing.
- Potential competitive advantages and winning new customers.

Medical Device Single Audit Program (MDSAP)

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DEKRA Medical Device Single Audit (MDSAP)

- DEKRA is a recognized MDSAP independent auditing organization.
- DEKRA's team checks and assesses, where appropriate, certifies compliance with the MDSAP requirements.
- DEKRA's experts have extensive knowledge of and experience with MDSAP and the requirements of the participating Regulatory Authorities: TGA in Australia, ANVISA in Brazil, Health Canada, MHLW and PMDA in Japan and FDA in the USA.

Benefits

- Fulfil all the compliance requirements in the Medical Device Single Audit Program (MDSAP) and participating regulatory authorities.
- Avoid multiple audits by each participating regulatory authorities, thereby reducing the number of annual audits and accelerating market entry.
- Mandatory for medical devices in Canada; advantageous for Australia, Brazil, Japan and USA.

CE Certification MDR

DEKRA CE Certification MDR

- DEKRA has two Notified Bodies (in Germany and the Netherlands) designated to offer conformity assessment of medical devices under the MDR so manufacturers can affix the CE marking to their products for access to the EEA market.
- DEKRA's experts check and assess the conformity of customers' products with all applicable requirements.
- Global coverage for on-site auditing of the development and production facilities.

Benefits

- Certification according to the requirements of the new MDR.
- Confirmation that the medical device meets the applicable requirements.
- Proof of compliance with the relevant EU safety requirements.
- Better access to markets adopting and/or recognizing the EU requirements including the EEA.

CE Certification IVDD/IVDR

CE Certification IVDD/IVDR

DEKRA CE Certification IVDD/IVDR

- DEKRA has two Notified Bodies designated to offer conformity assessment of in vitro diagnostic medical devices under the IVDD (Notified Body in the Netherlands only) and IVDR (Notified Body in Germany and eventually in the Netherlands), allowing manufacturers to affix the CE Marking to their products for access to the EEA market.
- DEKRA's experts check and assess the conformity of customers' products with all applicable requirements.
- Global coverage of on-site auditing of the development and production facilities.

Benefits

- Confirmation that the in vitro diagnostic medical device meets the applicable requirements.
- Proof of compliance with the relevant EU safety requirements.
- Better access to markets adopting and/or recognizing the EU requirements, including the EEA.