

DEKRA – Medical Devices Sterilization Expert & Auditor

What you are going to do

The DEKRA Medical division is a leading and fast-growing Notified Body within the Medical Device Industry. Consequently, we are looking for a medical device sterilization auditor and reviewer to join our team in the Netherlands. Dealing with cutting-edge medical innovations, we provide our clients with worldwide market access through executing conformity assessments for high-risk devices. We collaborate with a team of over 200 colleagues globally, all with the ultimate goal to ensure patient safety for medical devices.

Key Responsibilities

After completing an extensive internal training program at our office in Arnhem, you will:

- Independently execute audits (ISO 13485, EU MDR/IVDR, MDSAP) and sterilization reviews (EU MDR/IVDR), for medical device customers ranging from innovative start-ups to large multinationals.
- Act as an internal expert on sterilization, a part of the existing international sterilization team, supporting other non-specialist colleagues.
- Provide trainings internally and potentially externally (e.g. represent DEKRA at conferences).
- Travel within and outside Europe, approximately 30% of the time.

Your Qualifications and Experience

- A Bachelors or University level degree in a relevant science is a must [(micro)biology, (bio)chemistry, chemical engineering, (bio)physics, human physiology, medicine, pharmacy, material sciences, toxicology, veterinary medicine, biomedical science, genetics, physiology or closely related]
- A minimum of 4 years of full-time work experience in the medical device industry, including at least 2 years in Quality Assurance/Regulatory Affairs
- At least two years, hands on, in-house experience in at least one sterilization technology (e.g. EO, moist heat, chemical, aseptic processing), which should include being directly involved in sterilization validation activities (writing protocols, reports). Strong microbiology knowledge. Experience with more than one sterilization technology will be an advantage
- Experienced with medical device quality management systems and relevant laws and regulations (e.g. ISO 13485, EU MDR)
- Excellent English language skills (written and spoken)
- You are preferably already live in the Netherlands or are willing to relocate to the Netherlands

You will be given every opportunity to further develop the Medical approaches.

You work and collaborate closely together with experts worldwide in a collaborative work environment where your contributions are valued.

Our employees are our face and driving force. We offer an attractive salary and a good benefits package. We consider it important to give room for growth and development.

The position is based in the Netherlands.

More about DEKRA

DEKRA is one of the world's leading testing, inspection, and certification (TIC) companies, offering professional services in a wide variety of industries and technologies. As a purpose-driven organization with over 100 years of history and more than 45,000 employees in 60+ countries, DEKRA is committed to making the world a safer place, on the road, at work, and at home.

DEKRA Medical is a global leader in the certification of medical devices, including in-vitro diagnostic (IVD) devices. Operating through two Notified Bodies and one UK Approved Body, we serve customers across six regions.

At Medical, we are more than a regulatory checkpoint — we are a trusted strategic partner for medical device manufacturers. With a deep-rooted commitment to navigating complex regulatory frameworks, especially within the high-risk and innovative medical device sectors, we empower our clients to achieve market access and maintain a competitive edge.

Questions?

Please contact our corporate recruiter Misha Wittkowski (misha.wittkowski@external.dekra.com)

Please note: We manage our recruitment and selection entirely in-house. We do not appreciate acquisition by agencies or intermediaries. Submitting candidates without prior consultation and an explicit, written assignment from DEKRA does not establish any rights. Unsolicited profiles will be considered unrequested and will not be processed.

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