CE certification
Medical Devices

DEKRA
On the safe side.
Prior to launching a product on the European market it must comply with all applicable requirements in European legislation. The CE (Conformité Européenne) marking is the manufacturer’s declaration that a product fulfills all relevant regulations and standards, including safety, health and environmental protection requirements. All medical devices and in-vitro diagnostics marketed within the borders of the European Economic Area must fulfill the requirements set out in the Medical Device Directives, proving safety and performance, in order to affix the CE mark.

DEKRA Certification B.V. (DEKRA) – 0344 – is an accredited certification body that provides CE certification (MDD 93/42/EEC, AIMDD 90/385/EEC and IVDD 98/79/EC), optionally combined with ISO 13485 certification.

European Market Access Medical Devices

In order to assess whether DEKRA can be of service for CE certification of a medical device, the following documents will be required:
▶ A completed application form
▶ A copy of any relevant certificate(s)
▶ Brochure material, instructions for use, photographs, animations, and any other relevant (device) information

On receipt of the above mentioned information, DEKRA will issue a quotation to cover the work involved for the service(s) requested.

The Regulatory Pathway Review (RPR) is a pre-certification service offered by DEKRA prior to submission of the final technical documentation for CE certification. The goal of the RPR is to clarify on various elements of the proposed regulatory strategy related to safety and performance criticalities at the time of the final technical documentation submission. A RPR may include topics such as: biocompatibility protocol, clinical protocol, and list of applicable standards.

After acceptance of the quotation, a DEKRA project manager will be assigned to assist you during the CE certification process, which entails (1) a review of the technical documentation relating to the medical device and (2) an on-site audit. After receipt of the Technical Dossier, DEKRA requires 8 - 10 weeks to deliver the first report containing, if applicable, a list of questions and findings. The on-site audit will result in a report in which non-conformities are identified, if applicable. The client then responds to the findings and questions arising from the technical documentation review and provides a corrective action plan to address non-conformities identified during the on-site audit. Finally, when all questions and findings are satisfactorily addressed, a CE (0344) certificate will be issued.

In order to reduce the time to market, DEKRA may be able to offer an expedited review of the Technical Dossier. Instead...
of the normal 8 - 10 weeks of review time, DEKRA will provide the first report with a list of questions and findings 4 - 5 weeks after submission of the Technical Dossier.

The steps towards your successful CE certification

1. Get a proposal
   - Application form
   - Indication of costs and timelines

2. Choose DEKRA
   - Formal agreement
   - Assignment of one DEKRA project manager
   - Planning

3. DEKRA Certification activities
   - Off-site review of your technical documentation
   - On-site CE audit

4. Get your certificate
   - Verification of compliance by DEKRA Certification Management
   - Your CE certificate

Validity of Your CE certificate

After receiving the CE certificate for a medical device, all documentation and processes relating to product safety and performance must be maintained by the legal manufacturer. The CE certificate is valid for three years after initial issue by DEKRA, after which time the certificate must be renewed.

Surveillance Audit

Once a certificate has been issued, the surveillance phase will commence and DEKRA will visit the location(s) of the client on an annual basis. The purpose of a surveillance audit is to confirm that the CE certified medical device and the related quality procedures continue to fulfil all regulatory requirements.

Renewal Audit

At the completion of the certification cycle, your DEKRA project manager will generate a plan for the client to begin another three-year registration period. The renewal audit is typically scheduled to occur three months before the certificate expiration date. During the renewal process, the effectiveness of the entire quality system in light of internal and external changes will be reviewed and audited with respect to its continued relevance and applicability to the scope of the certification. In case of TE and / or DE certification, DEKRA Certification expects the client to lodge a formal Renewal Application in a timely manner; at least three months prior to expiry of the certificate(s).

Subcontractor Audit

Depending on the amount of outsourced activities by the client, additional time may need to be allocated for subcontractor audits. Whether an (additional) audit at a subcontractor’s premises is deemed necessary depends on the determination that sufficient controls are applied and demonstrated by your QMS. Therefore it is important to inform DEKRA concerning all involved (critical) subcontractors and suppliers.

Unannounced Audit

DEKRA performs unannounced audits in accordance with the new European regulations and recommendations for Notified Bodies. Following a risk evaluation of your CE marked product lines, DEKRA may conduct unannounced audit(s) at your premises and/or critical production, subcontractor or supplier locations. Unannounced audits are not applicable to only ISO 13485 certified companies.

Vigilance

In line with recent regulations to increase the effectiveness of post market surveillance, on-going assessment of all reportable incidents and recalls is required by the Notified Body. Therefore, in accordance with the certification and our General Terms and Conditions, it is required to notify DEKRA Certification, along with the relevant regulatory authorities, of all reportable incidents and recalls related to medical devices covered by the certification.

Contact for further questions
Phone: +31 88 96 8309
Email: medical.nl@dekra.com
www.dekra-certification.com/medical