Conformity Assessment Procedure for Medical Devices under the MDR

European Market Access Medical Devices

Prior to launching a product on the European market it must comply with all applicable requirements in European legislation. The CE (Conformité Européene) marking is the manufacturer's declaration that a product fulfils relevant regulations and standards, including safety, health and environmental protection requirements. All medical devices marketed within the borders of the European Economic Area must fulfil the requirements set out in the Medical Device Regulation (MDR) (2017/745), proving safety and performance, in order to affix the CE mark.

DEKRA Certification GmbH (DEKRA) is a Notified Body which is designated in Europe for the MDR. DEKRA also provides ISO 13485 and MDSAP Certification.

MDR Pre-application

Should you be interested in having devices certified under the MDR by DEKRA, a pre-application is first required. The following documents should be submitted for the pre-application:

> A completed Company Information Form (CIF)
> A copy of any relevant certificate(s)
> Brochure material, instructions for use, photographs, animations, and any other relevant (device) Information

Based on a review of the above documents, DEKRA will determine whether it is accredited and able to provide the requested conformity assessment services. Please note that the Technical Documentation, QMS documents and related correspondence can only be accepted by DEKRA in German or English.

Once it has been determined that DEKRA can offer the required services, a quotation will be compiled and provided.

MDR Application

After acceptance of the quotation by a manufacturer the MDR application process can start. A DEKRA Project Manager will be assigned and a Medical Application Form will need to be completed by the manufacturer. This must be provided to DEKRA, along with any other supporting documentation. The DEKRA Project Manager starts with the formal application review, after which the Certification Agreement is established.

At the end of the application phase the TD review activities and audit activities will be planned.

MDR Technical Documentation Review and On-Site Initial Audit

Once the manufacturer has submitted the Technical Dossier, DEKRA shall perform a quick scan on completeness of the file. When approved, the technical file review will start at an agreed date. After the review DEKRA shall 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, if applicable, are identified. The manufacturer provides a corrective action plan to address non-conformities identified during the on-site audit and submits evidence of correction of the findings. Finally, when both the technical documentation review and audit have satisfactory results, the relevant certificates under the MDR can be issued for CE-marking of the identified device(s).

Please note, that the relevant certificates under the MDR must be issued within 12 month of the audit taking place. If technical documentation review and/or the audit have no satisfactory results by then an additional, initial audit will be required.

Summary of the steps towards CE marking of Medical Devices under MDR

Guiding you through the conformity assessment process: from (pre-) application at DEKRA to CE Mark certificate being issued.

1. Pre-application process

Obtain a quotation
> Submit Company Information Form and accompanying documents
> Response from DEKRA following pre-application review of the provided information
> Indication of costs and timelines provided by DEKRA (quotation)
Required documents in this phase:
• A completed Company Information Form (CIF)
• A copy of any relevant certificate(s)
• Brochure material, instructions for use, photographs, animations, and other relevant (device) information

2. Application process

You have accepted the quotation of DEKRA
> Submit Medical Application Form with supporting documents
> Assignment of a Project Manager by DEKRA
> Application review by DEKRA of the provided form and related documents
> Establishment of a Certification Agreement between DEKRA and the manufacturer
> Scheduling of technical documentation review and Audit activities

3. Review and Audit activities

Start and planning of the review and audits
> Submit technical documentation*
> Off-site review of technical documentation by DEKRA
> On-site audit at the manufacturer
> On-site audit at critical suppliers (if deemed necessary)
* Once the manufacturer has submitted the Technical Dossier, DEKRA shall perform a quick scan on completeness of the file. When approved the technical file review will start at an agreed date. After the review DEKRA delivers the first report containing, if applicable, a list of questions and findings

4. Certification

When the review and the audits have satisfactory results (device and QMS are verified to be in compliance with the MDR the relevant certificates under the MDR can be issued
> Verification of compliance by DEKRA Certification Management
> Issuance of certificates under the MDR



Validity of Your CE certificate

After receiving the relevant MDR certificate, all documentation and processes relating to product safety and performance must be maintained by the manufacturer. In principle, the certificates will be valid for five years after initial issuance by DEKRA, after which time the certificates must be renewed.

Surveillance Audit

Once the MDR certificates have been issued, the surveillance phase will commence and DEKRA will visit the location(s) of the manufacturer on an annual basis. The purpose of surveillance audits is to confirm that the CE-certified medical devices and the related quality processes continue to fulfil all regulatory requirements.

Renewal Audit

At the completion of the certification cycle, the DEKRA Project Manager will generate a plan to begin another five-year certification 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 management system within the context of internal and external changes will be reviewed and audited with respect to its continued relevance and applicability to the scope. In case a technical documentation assessment certificate or a type examination certificate has been previously issued, DEKRA expects the client to lodge a formal Renewal Application in a timely manner; at least 6 months prior to expiry of the certificate(s).

Subcontractor Audit

Depending on the type of activities outsourced by the manufacturer, additional time may be allocated for subcontractor audits. Whether an (additional) audit at a subcontractor's premises is deemed necessary depends on the type and extent of control the manufacturer has over the subcontractor's activities. Therefore it is important that DEKRA is informed about all involved (critical) subcontractors and suppliers.

Unannounced Audit

DEKRA performs unannounced audits at manufacturer's premises which hold a CE certificate in accordance with the European regulations. Following a risk evaluation of the CE-marked product lines, DEKRA may conduct unannounced audit(s) at the manufacturer's premises and/or critical production, subcontractor or supplier locations as listed on the DEKRA Certification Notice.

Vigilance

In line with regulations to increase the effectiveness of post market surveillance, an on-going assessment of all reportable incidents, field safety corrective actions (FSCAs), field safety notices (FSNs) and recalls is required by the Notified Body. Therefore, in accordance with the Certification Agreement and DEKRA General Terms and Conditions, it is required that the manufacturer notify DEKRA, along with the relevant regulatory authorities, of all reportable incidents, FSCAs, FSNs and recalls related to medical devices covered by the certificate(s).

Change notifications

Once certified, the manufacturer is obliged to notify DEKRA of changes to a certified device(s) and quality management system according to MDR 2017/745.

This includes changes to:

- Approved quality management system(s) or product-range covered;
- Approved design of device;
- Intended use and claims made for the device;
- Approved type of device;
- Any substances incorporated in or utilized for manufacturing of a device;
- Changes that could impact compliance with the GSPR or CS or other solutions which were approved previously;
- Legal, commercial, organizational status or ownership;
- Organization and management (e.g. key managerial, decision-making or technical staff);
- Contact address and sites;
- Scope of operations under the certified management system;
- Major changes to the management system and processes.

DEKRA Certification GmbH - NB0124
DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Germany

Tel. +49 711 7861 3771

Certificaton.de@dekra.com
www.dekra-certification.de