DEKRA Certification

Program requirements QMS auditing services

QMS auditing services by DEKRA

In order to demonstrate that the processes involved in the design & development, production, and servicing meet the expected outcomes, companies might be required to implement a quality management system (QMS). Typically, QMS requirements are demonstrated using ISO standards such as ISO 9001 and ISO 13485.

ISO 13485 and ISO 9001 standards are internationally recognized and harmonized QMS standards, developed for various industries including the medical device industry. They provide guidance and tools to create an effective QMS that ensures product and service quality. ISO QMS standards are not mandatory, but increasingly considered to be the basis for CE / UKCA certifications in industries such as the medical device industry.

DEKRA Certification (DEKRA) is an accredited certification body that provides ISO QMS certification, optionally combined with CE and UKCA certification.

Our ISO scopes can be found here:

- DEKRA Certification B.V. RvA
- DEKRA Certification UK Ltd UKAS

Contact DEKRA

In order to assess whether DEKRA can be of service for ISO QMS certifications, the following documents will be required:

- A completed company information form
- A copy of any relevant certificate(s)
- Any relevant brochure material

When DEKRA can be of service to your organization, a quotation will be issued. Please note that the QMS documents and related correspondence can only be accepted by DEKRA in English.

Certification Process

After acceptance of the quotation, a DEKRA project manager will be assigned to assist you during the ISO QMS certification process. The certification process consists of an on/off-site stage 1 ISO QMS readiness audit and an on-site stage 2 ISO QMS certification audit.

Stage 1: Readiness audit

The purpose of the stage 1 ISO QMS readiness audit is to verify the readiness of the organization's quality management system in preparation for the stage 2 audit. Typical topics of a stage 1 audit include:

- a review of the management system documentation
- review of the client's status and understanding regarding requirements of the standard
- determination of the scope of the management system
- identification of critical suppliers and critical subcontractors, to determine whether sufficient time is allocated for the stage 2 certification audit
- evaluation of the planning and performance of internal audits and the management review process.

The readiness audit shall confirm the planned audit duration for stage 2 certification audit. Revision of the quotation might be appropriate.

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Stage 2: Certification audit

The stage 2 ISO QMS certification audit will be planned after sufficient time has been allocated to correct any issues and concerns identified during stage 1. Prior to conducting a stage 2 ISO QMS certification audit, **a full round of internal audits and a complete management review should be performed**. The purpose of a stage 2 ISO QMS certification audit is to evaluate the implementation and effectiveness of the quality management system.

The audit will result in a report that may include nonconformities identified. You will receive an initial report, including nonconformities, at the end of the audit during a presentation at the closing meeting. Based on the outcome of the stage 2 ISO QMS certification audit, the client shall respond to nonconformities identified and provide a corrective action plan.

After completion of the stage 2 ISO QMS certification audit and closure of each nonconformance, DEKRA will recommend ISO QMS certification. DEKRA then performs a final review of all reports and relevant client data to determine if the client fully complies with the requirements. After this review an ISO QMS certification will be granted.

The steps towards your successful ISO QMS certification

1. Get a proposal

- Company Information Form
- Response from DEKRA following pre-application review of the provided information
- Indication of costs and timelines

2. Choose DEKRA

- Submit Medical Application Form with supporting documents
- Formal agreement
- Assignment of one DEKRA project manager
- Application review by DEKRA of the provided form and related documents
- Planning

3. DEKRA Certification activities

- On-site ISO QMS audit

4. Get your certificate

- Verification of compliance by DEKRA Certification Management
- Your ISO QMS certificate

Validity of your ISO QMS certificate

After receiving the ISO QMS certificate, the quality management system must be maintained by the certificate holder. The ISO QMS certificate is typically valid for three years after initial issue by DEKRA, after which the certificate must be renewed.

Surveillance audit

Once a certificate has been issued, the surveillance phases will commence and DEKRA will visit the location(s) of the client on an annual basis. The first surveillance audit after initial ISO certification must be conducted within one year of the last audit day of the stage 2 audit. During the surveillance audits, processes identified in the audit matrix will be audited as well as any process changes or additions.

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 is assessed. Any internal and external changes will be reviewed and audited with respect to its continued relevance and applicability to the scope of the certification.

Subcontractor audit

Depending on the number of outsourced activities by the client, additional time will 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.

Suspension, restoration, or withdrawal of your certificate

When an ISO QMS certificate holder does not meet the requirements of the certification agreement, DEKRA will inform the client of the possible consequences. If conditions and timelines are not met this can result in a certificate suspension or withdrawal of the certificate. While the suspension of a certificate is in effect, the client shall not claim conformity towards the applicable standard. Duration of the suspension period is typically three months but should never exceed a 6 month period.

DEKRA shall restore the suspended certification once the issue that resulted in the suspension has been resolved. Failure to resolve the issues that resulted in the suspension in a reasonable time established by DEKRA shall result in withdrawal or reduction of the scope of certification. In the case of withdrawal of certification, this cannot be reversed. When you wish to be certified again this shall only be through an initial certification procedure.

An ISO QMS certificate holder can voluntarily request cancellation of the certificate or the underlying certification agreement. This request should be formalized by DEKRA and formally communicated through a cancellation letter to the certificate holder.

Extension or reducing the scope of your certificate

In the case it could not be demonstrated that the assessed QMS is fully covered by the certificate, the scope of the certificate shall be reduced or a certificate with a limited expiration date will be issued until the required conditions are met.

A DEKRA client can request to expand the scope of certification to include, for example, additional activities or production sites. This scope extension audit can be scheduled in conjunction with a surveillance audit or renewal audit, typically resulting in additional audit duration.

Use of logos

The manufacturer is authorized to use the DEKRA logo on printed materials such as letter headings and envelopes, or to otherwise publish, once certification is granted. It must be clear in all circumstances that the DEKRA logo refers to the organization or process in its entirety, ensuring this is covered within the scope. The manufacturer is not authorized to affix the DEKRA logo on products or to make use of the DEKRA logos in advertisements for products. Reports by certified laboratories, calibration bodies or inspection bodies are seen as products of these bodies. The format of the DEKRA logo is authorized to be modified on condition that the original color and the original proportions are unaltered. No authorization to modify the color of the DEKRA logo is granted. Use of black or white is permitted.

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