DEKRA Quality Management System

Certification Services



Introduction

Demonstrate Quality. Achieve Compliance. Build Confidence.

A robust Quality Management System (QMS) enables organizations to consistently deliver safe, reliable, and high-quality products and services.

Internationally recognized standards such as ISO 13485 and ISO 9001 provide proven frameworks for establishing and maintaining an effective QMS. While ISO 9001 is applicable across a wide range of industries, ISO 13485 is specifically developed for medical device manufacturers and related organizations, supporting regulatory compliance, product quality, and patient safety. ISO 9001 certification is available exclusively in combination with ISO 13485.

In addition to ISO certification, DEKRA is recognized to perform **Medical Device Single Audit Program (MDSAP)** audits and is designated to support regulatory market access in regions such as **Singapore (SAC**), **South Africa (SAHPRA)** and **Taiwan (Technical Cooperation Program – TCP)**, enabling manufacturers to streamline regulatory compliance across multiple jurisdictions.

Our recognitions and designations can be found here: Our accreditations and recognitions

Start Your Certification Journey



To help us understand your organisation's needs and how DEKRA can support you with ISO QMS certification, we'll need the following information:

- Completed Company Information Form
- Copies of any existing certificates
- Relevant company brochures or supporting documentation

Once we have received your information, we will carry out a pre-application check to ensure we can be of service and provide a detailed quotation. This will outline the proposed certification activities, expected timescales and associated costs.

Please note: All QMS documentation and related correspondence submitted to DEKRA must be provided in **English.** On the next page, we outline the steps of our certification process.

The DEKRA Certification Process
After acceptance of the quotation, a DEKRA project manager will be assigned to assist you during the ISO QMS certification process.

Certification steps explained

01

Request a Proposal

- Complete the Company Information Form
- Submit supporting information
- Obtain a quotation including costs and timelines

02

Confirm Your Application

- Submit the Medical Application Form and supporting documentation
- Sign the certification agreement
- Application review and audit planning

03

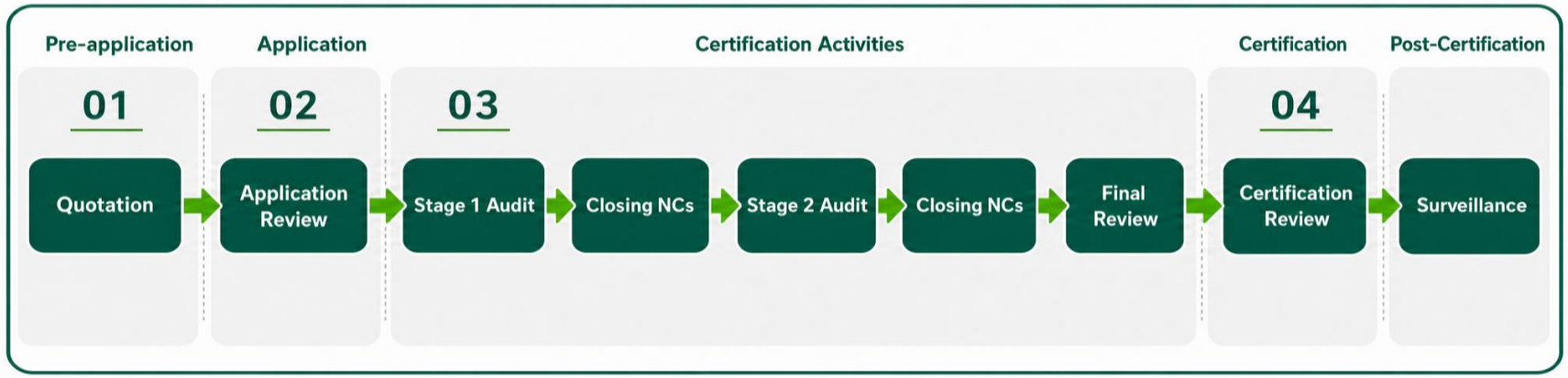
Certification Activities

- Stage 1 Readiness Audit
- Stage 2 Certification Audit
- Resolution of any identified nonconformities

04

Certification and On-Going Support

- Final technical review by DEKRA Certification Management
- Issuance of your ISO QMS Certificate



Your Path to Certification

Stage 1 – QMS Readiness Audit
The Stage 1 audit evaluates whether your Quality Management System is adequately prepared for the certification audit.

The audit typically includes:

- Review of Quality Management System documentation
- Assessment of the organization's understanding of applicable ISO requirements
- Confirmation of the certification scope
- Identification of critical suppliers and subcontractors
- Evaluation of internal audits and management review activities
- Confirmation of the audit duration required for Stage 2

Where necessary, the audit plan or quotation may be adjusted based on the findings.

Stage 2 – Certification Audit
The Stage 2 audit assesses the implementation and effectiveness of the Quality Management System.

Before this audit, organizations should have:

- Completed a full cycle of internal audits
- Conducted a comprehensive management review
- Addressed observations identified during Stage 1

Following the audit, DEKRA provides an audit report detailing any identified nonconformities.

Organizations are required to:

- Respond to all nonconformities
- Submit corrective action plans
- Demonstrate implementation of corrective actions

Once all nonconformities have been satisfactorily closed, DEKRA performs a final review. Upon successful completion, an ISO QMS certificate is issued.

Managing Your Certification

ISO QMS certificates are generally valid for **three years**, provided the Quality Management System continues to meet certification requirements.

Annual Surveillance Audits
Once certification has been achieved, DEKRA carries out annual surveillance audits to make sure your organisation continues to meet the required standards.

These audits typically focus on areas such as:

- Key management system processes
- Any changes to products, processes or the organization
- How effectively corrective actions have been implemented
- Ongoing compliance with certification requirements

Renewal Audit
At the end of the three-year certification cycle, a renewal audit is carried out to review the overall effectiveness of your Quality Management System to ensure it continues to meet the required standards. This audit usually takes place around three months before your certificate expires and included a full review of your management system, consideration of any organisational changes and an assessment of continued compliance with the relevant standards. Once successfully completed, your certification can be renewed for a further three-year cycle.

Subcontractor Audits
If your organisation outsources any critical activities, additional audit time may be needed to assess the relevant subcontractors or suppliers. Whether these audits are required will depend on:

- The criticality of the outsourced activities
- How effectively suppliers are managed and controlled within your QMS
- The level of oversight your organisation has over subcontracted activities



Managing Your Certification

Suspension, Restoration, or Withdrawal of Your Certificate

If your organisation does not meet the requirements of the certification agreement, we will let you know of any potential consequences and explain any corrective actions needed, along with the relevant deadlines. If the required actions are not completed within the agreed timeframe, your certificate may be suspended or withdrawn.

During the suspension period, you cannot claim that your Quality Management System (QMS) conforms to the applicable standard on the basis of the suspended certificate. The suspension period is normally three months and shall not exceed six months.

We will restore your certificate once the issues that led to the suspension have been satisfactorily resolved. If you do not resolve these issues within the timeframe we have set, we may withdraw your certificate or reduce the scope of your certification, depending on the situation

Withdrawal of your certificate is final and cannot be reversed. If you wish to obtain certification again following withdrawal, you have to undergo a new initial certification process.

You can also choose to voluntarily request the cancellation of your certificate or the underlying certification agreement. We will record your request and confirm the cancellation in writing with a formal cancellation letter.



Managing Your Certification

Extension or Reduction of the Scope of Your Certificate
During the assessment, if we determine that your Quality Management System (QMS) does not fully cover the proposed certification scope, we may need to reduce the scope to reflect what is covered. Where appropriate, we may also issue a certificate with limited validity until the necessary requirements have been met.

You can also request an extension of your certification scope to include additional activities, products, or production sites, as applicable. We can arrange the scope extension assessment alongside your next surveillance or recertification audit, where appropriate.

Use of the DEKRA Logo
Once your organisation has achieved certification, you can use the DEKRA logo on printed materials, such as letterheads and envelopes, as well as in other publications. Any use of the logo must clearly relate to your organisation or the activities covered by your certification scope.

The DEKRA logo must not be placed directly on your products or used in product advertising in a way that could suggest the products themselves have been certified by DEKRA. Please also note that reports issued by certified laboratories, calibration bodies or inspection bodies are considered products of those organisations and are subject to the relevant restrictions on DEKRA logo use. If you have any questions regarding the requirements for the use and reproduction of the DEKRA logo, please refer to document #4471 or contact your DEKRA project team.



Global Recognition and Regulatory Support

Global markets

DEKRA's Quality Management System (QMS) certification services are supported by internationally recognized accreditations and regulatory programs, helping manufacturers demonstrate compliance across multiple global markets.

Medical Device Single Audit Program (MDSAP)

DEKRA is recognised to perform audits under the **Medical Device Single Audit Program (MDSAP)**. MDSAP allows manufacturers to undergo a single regulatory audit of their Quality Management System (QMS). The audit evaluates compliance with ISO 13485:2016 as well as the applicable regulatory requirements of each participating country, providing an efficient pathway to demonstrate compliance across multiple international markets.

The MDSAP participating regulatory authorities include:

- Australia – Therapeutic Goods Administration (TGA)
- Brazil – Agência Nacional de Vigilância Sanitária (ANVISA)
- Canada – Health Canada (mandatory)
- Japan – Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)
- United States – Food and Drug Administration (FDA)

Affiliate Member:

- United Kingdom – The Medicines and Healthcare products Regulatory Agency (MHRA) is currently an Affiliate Member and has announced its intention to work towards full participation in MDSAP.

Global Recognition and Regulatory Support

Singapore Accreditation Council (SAC)
Medical device companies in Singapore are required to be licensed by the Health Sciences Authority (HSA) to manufacture, import, or supply by wholesale. Manufacturers, importers, or wholesalers with a location in Singapore can apply for ISO 13485 certification under SAC accreditation. DEKRA Certification B.V. is accredited by the Singapore Accreditation Council (SAC) to issue ISO 13485:2016 certificates. This supports manufacturers, importers, and distributors in meeting the quality system requirements for regulatory compliance in Singapore.

South African Health Products Regulatory Authority (SAHPRA)
For manufacturers seeking access to the South African medical device market, DEKRA's ISO 13485 certification supports compliance with the Quality Management System expectations of the South African Health Products Regulatory Authority (SAHPRA). An effective ISO 13485-certified QMS assists manufacturers in demonstrating that their products are designed, manufactured, and controlled in accordance with internationally accepted quality management principles.

Technical Cooperation Programme III (TCP III)
DEKRA participates in the Technical Cooperation Programme III (TCP III), which facilitates the exchange of regulatory audit reports between EU Notified Bodies and authorized auditing organizations in Taiwan.

Participation in TCP supports manufacturers seeking market access in Taiwan by enabling the recognition of EU audits for regulatory purposes. Compliance with Good Manufacturing Practice (GMP) and ISO 13485 requirements plays a key role in the acceptance of audit outcomes by the Taiwan Food and Drug Administration (TFDA).

Contact us for more information

Talk to our experts

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