

The Certification Process in DGM

DGM is a business unit in DS Certificering A/S and a provider of certification services for the medical device industry.

DGM offers certification according to:

- The Medical Device Directive (MDD) and the In Vitro Diagnostic Directive (IVD)
- ISO 13485:2003 and ISO 9001:2008

Furthermore, DGM offers the following services:

- FDA inspections of medical device manufacturers (Appointed Person Program)
- ISO 13485 audits under CMDCAS, the CMDCAS audits are carried out on behalf of SAI-QMI, a SCC recognised registrar¹.
- Audits according to the Taiwanese requirements. The registration process of your product(s) in Taiwan is eased² by having DGM carry out audits incl. the Taiwanese requirements.

DGM services are provided in Europe and North America mainly, however, not exclusively.

How to obtain certification according to the MDD, IVDD, ISO 13485 or ISO 9001

The process involved in obtaining certification varies according to your requested certification type.

The certification process for MDD, IVD directive, ISO 13485 and/or 9001 certifications is described below in the section "System Certification Process".

The certification process for type and/or design examinations is outlined below in the section "Type Approval".

Quotes and Applications

Quotations

At your request DGM provides a quote for your chosen certification.

In order for DGM to issue a quote for your company, we ask you to fill in and submit the DGM questionnaire, which you can download from DGM's websites: www.dscert.dk/da-DK/DGM/English/Sider/DGM_UK.aspx (English language) or www.dscert.dk/da-DK/DGM/Sider/DGM.aspx (Danish language)

¹ The processes explained here cover the most common conformity assessment routes to obtain CE marking of medical or in vitro diagnostic devices. Alternative routes (may) exist depending on class of the device in question. Please contact DGM for further information.

² The processes explained in this document do not apply to audits according to the Taiwanese requirements, please contact DGM for information.

Applications

Once you have selected DGM as your registrar/notified body, you submit the signed application form and the documentation requested on this form.

DGM then reviews your application to ensure that we have the notifications, competences, resources and the documentation needed to initiate your certification.

When the review is complete, we will send you a copy of the contract and an order confirmation with information regarding where on our website you can find various documentation and templates that will assist you in the certification process and which Lead Auditor is to be your future point of contact to DGM.

System Certification Process

The certification cycle for system certifications is three years. You start with the certification phase followed by two years of annual surveillance audits.

A recertification audit is required to take place at the latest 3 years after the certification audit. The recertification audit initiates a new 3 year cycle and is followed by two years of annual surveillance audits. Subsequent cycles follow the same model, i.e. a recertification initiates the cycle and is followed by two years of annual surveillance audits.

Certification

The certification consists of 2 main phases:

Evaluation, is your company ready for a certification audit?

This evaluation is in part carried out at DGM and at your facility.

DGM evaluates your implemented quality system against the requirements and your product information (selected elements of your technical file). Normally we also visit your facility in order to verify that the system is in place and to ensure that we allocate the right resources for the upcoming audit.

The result of the evaluation, including any existing or potential non-compliance, is reported to you in a pre-assessment report. Depending on the severity and number of (potential) non-compliances, we determine if we need to have documentation for the correction of the problems identified prior to performing the certification audit.

Certification audit

The certification audit phase is when the audit itself takes place.

Based on an audit program sent to you well in advance of the audit, we conduct a full audit of your quality management system and your products to verify that you comply with the requirements.

During the audit we will compile objective evidence of your compliance by interviewing personnel, look at procedures, products and the general implementation of the quality system etc.

Based on the objective evidence compiled we will make our conclusions, as to which parts of the quality system/products that are in compliance and which are not. The result of the audit is reported to you at the closing meeting, where any nonconformities are presented to you as well. An audit report summarizing what was presented to you at the closing meeting is sent to you subsequent to the audit.

Nonconformities represent areas which must be addressed by you to ensure compliance. Evidence that you are in compliance must be documented, submitted to and accepted by your auditor and in some cases we may need to audit the closure of the nonconformities or re-audit certain areas of your quality system.

After the audit and the closure of the nonconformities, should any have been identified, a DGM person, not part of the audit team, reviews the documentation from the audit to verify that everything has been performed correctly. After this verification has taken place your certificate is issued and sent to you.

Surveillance audits

In order for you to maintain your certification, DGM has to verify your company's continued compliance with the requirements. This verification is usually carried out annually for two years, in the form of surveillance audits.

Surveillance audits are conducted according to the audit program sent to you prior to the audit, and the audit typically covers certain areas of the quality system and/or your products. Please note that the duration of a surveillance audit is shorter than the certification audit.

As with the certification audit, the result of your audit (incl. nonconformities, should there be any) is reported to you at the closing meeting, and the audit report is sent to you subsequent to the audit.

Once the audit is finalized, any non-conformities have been closed, and the closure is accepted by DGM, we confirm the continued validity of your certification. In some cases we may need to audit the closure of the non-conformities or re-audit certain areas of your quality system.

DGM also offers you the possibility of having surveillance audits performed every 6 months which may be relevant for a "young" company, a "young" quality system, if your company is undergoing changes or perhaps just because you want to maintain focus on the system.

Recertification audit

Every third year the surveillance audit is replaced by a recertification audit. The recertification is, as the certification phase, conducted in two steps, however, both of these are less time consuming than those of the certification audit.

Step one of the recertification consists of an evaluation of your quality system documentation, and once again the evaluation is reported to you in a pre-assessment report sent to you prior to the audit. The pre-assessment is performed in order to document that the changes made since the certification has not impacted your quality system in such a way that it is no longer compliant with the requirements. It also ensures that the system is up to date with the interpretation of the regulatory setting.

Should DGM find any issues during the pre-assessment, these shall be solved and the evidence documented to DGM at the latest at the opening meeting of the recertification audit. In certain cases DGM may require that these issues are documented closed to DGM prior to the recertification audit and/or require a visit to your facility (please see "Evaluation, is your company ready for a certification audit?")

Step two is the recertification itself. The audit and the subsequent activities (please see "Certification Audit") are carried out like the certification audit, and subsequent to the independent review your certificate is reissued. Please note that the duration of the recertification audit is shorter than that of the certification audit.

Product Certification (type examination, design examination)

DGM's designation as notified body also covers design and type examinations of medical and in vitro diagnostic devices according to the MDD and IVDD respectively.

Please note that design and/or type examinations are not an option for all classes of devices.

The certification of a product is based on an evaluation and acceptance of the design dossier/technical file of your product(s) and the product in question if necessary.

DGM evaluates the design dossier/technical file and reports the result to the company. If compliance cannot be established based on the submitted design dossier/technical file observations are issued, these observations represent non-conformities which are to be addressed in order to establish compliance with the requirements and DGM has to verify this compliance. Please note that DGM may have to involve a competent authority or EMEA for the approval of some products.

As products subject to a type or design examination and the certification of a quality system "producing" the devices are mutually dependant, the certificate of the product (type examination or design examination) is issued at the same time as the certificate for the quality system. Furthermore, as DGM has to evaluate the capability of a company's quality system to produce the device in question, the full certification audit of the system cannot be conducted prior to the finalization of the evaluation of the design dossier/technical file.

Design examination and type examination certificates have a validity of 5 years. If the certification is to be extended, the design dossier/technical file, and/or any changes to it, has to be re-evaluated.

Changes to the Certification

No system remains the same forever and changes of a significant nature are often implemented to a company's quality system, the company itself or its products, e.g.: New quality system, extended scope of the services provided by your company, outsourcing/change of processes, new or changed products etc. Any such changes must be reported to DGM. We then evaluate the changes and conduct the activities needed for us to maintain the certification. The coverage of the activities depends on the nature of the change; these can range from a simple acceptance from us to an audit. Depending on the nature of the change and the certification issued, it may or may not be acceptable to conduct the change prior to our acceptance.

Likewise, DGM may need to change the certification or conduct additional activities. This typically occurs if there are changes to the regulatory requirements or the standards.

Cancellation, Suspension and Withdrawal

As the certifications by DGM document the compliance of companies or products, DGM has the ability to withdraw a company's certificate if the company or the product(s) no longer comply with the requirements.

In most cases DGM and the company agree on an action plan for resolving any non-compliance/nonconformities, however, if DGM and the company cannot come to an agreement or if the non-compliance(s) is of a significant nature, DGM may be forced to withdraw the certification. Should the company request certification again, it is normally required that the certification cycle starts over.

The customer can cancel the certification agreement with DGM and/or any certifications provided that a reasonable notice (3 months) is given. DGM also has the right to cancel the certification agreement with a company – again provided that a reasonable notice (6 months) is given. Should the company request certification again, it is required that the certification cycle starts over i.e. starting at the certification phase.

As a customer of DGM you also have the right to suspend a certification for up to 3 months. This option allows you to put the certification on hold, without having to start the certification cycle all over.

Once a certificate is withdrawn, the certification terminated or the certification suspended the company must refrain from using the certificates and from promoting the certification.