
1. Auditing and Certification Services

1.1 Scope and Applicability

These DQS Auditing and Certification Regulations apply to all auditing and certification services offered and rendered to clients of the international DQS Group, including all its subsidiaries and partners. A current list of all members of the DQS Group is available at www.dqsglobal.com. These regulations apply throughout all stages of the auditing or certification process, including but not limited to service offers and quotations, contracts, purchase and/or work orders, schedules and addendums agreed to between DQS and Client, unless it is otherwise explicitly agreed in writing or so prescribed by statutory instruments.

These Auditing and Certification Regulations become effective as of January 1st, 2026 and remain valid until a new version is issued and published.

The current version of these regulations is available in German and English language on the website of DQS MED (www.dqsglobal.com) and can be requested from DQS MED.

1.2 Definition of terms

“Client” stands for customers and any organization that inquires about or receives any DQS auditing or certification service, including their representatives, who act on their behalf.

“DQS” stands for any group members of the international DQS Group, including its subsidiaries and partners, who offer and/or deliver auditing and certification services to clients. In some cases one group member may become the contractual local partner of a client, while a specific service may be delivered partially or in full by another group member.

“Auditor” stands for assessors, auditors and experts, who are assigned to an auditing and certification process on behalf of the DQS group.

1.3 Auditing and Certification Services

The auditing and certification of a management system or a product by an independent, competent third party, such as DQS MED, generates valuable benefits for the client. A DQS certificate will serve as evidence for a suitable and effective management system or compliant product with the capability to continuously meet customer expectations as well as regulatory and statutory requirements.

During an audit, qualified and experienced auditors review the management system and its processes or products for ongoing suitability and effectiveness in light of changing markets and environment. By identifying improvement potential, auditors enhance the organization’s ability to meet established goals and objectives, thus enhancing sustainable success for the client. With a DQS MED certificate customers may place confidence in the client and the certified management system or product, which has been audited and certified to recognized standards and specifications.

1.4 Reference to individual contract and commercial terms

1.4.1 These conditions apply to contracts agreed between DQS MED and its customers, unless otherwise agreed in written form or regulated by a statutory authority.

In the following text, audits and assessments are referred to as “assessments”, auditors and experts as “assessors”, audit and assessment reports are referred to as “assessment report”, certification documents are referred to as “certificates”.

- 1.4.2 The customer accepts the General Terms and Conditions, the Audit and Certification Regulations and the Price List in their current versions as well as the prices as agreed in the order confirmation.
- 1.4.3 Differing terms and conditions from individual customers are generally not accepted.
- 1.4.4 Side agreements, commitments and other statements from employees of DQS MED or from involved assessors become only binding, if they are confirmed in writing by DQS MED. This applies also to changes of this clause.

2. The Certification Process

DQS audits the Client’s management system or product, or parts thereof, with the goal of determining its conformity with agreed and acknowledged requirements, such as international, national or sector-specific standards or specifications. The respective certification process may involve one or more steps, usually ending with an audit report, which documents the audit results. In the case of certification services, DQS will issue a customer-specific certificate, confirming conformity to the respective requirements, when the fulfilment of all applicable requirements has been evident.

If nonconformities with requirements of the respective standard or specification have been identified during an audit, corrective action shall be planned and carried out by Client within a specified timeframe. Certificates will only be issued after the effective deployment of suitable corrective action has been demonstrated. The scope and duration of validity shall be stated on the certificate.

DQS and Client agree that the evaluation and/or certification of the Client’s management system(s) or products shall be performed in accordance with the applicable standards, the industry related requirements (if applicable) and the Auditing and Certification Agreement, including this document and any documents attached thereto or referred to therein. DQS is independent, neutral and objective in its audits and certifications. Audits are performed at Client’s place of operations. The type, extent and time schedule of the procedure are subject to separate agreement by the parties. DQS strives to minimize any disturbances of the business process while conducting the audit on Client’s premises. The Certification Process for management systems will generally include the steps mentioned at the end of this document.

3. Rights and Obligations of Client

3.1 Maintaining the Management System

In order to obtain and maintain a certificate, the Client shall implement and maintain a documented management system which fulfills the requirements of the selected standard or specification. The Client shall provide evidence of conformity and effectiveness of the audited management system or product, readily available for auditing by the assigned audit team. The Client shall undertake all necessary actions to ensure that the management system is maintained in a conforming and effective manner at all times.

The Client shall be notified of any changes to the certification program or new or revised requirements. In case the certification applies to ongoing production, the Client shall ensure that the certified product continues to fulfill the system or product requirements. DQS shall verify the implementation of changes by the Client and initiate required measures in the certification process.

3.2 Burden of Production ("accessible information" according to ISO/IEC 17021)

The Client ensures that DQS has access to all necessary information and the requisite facilities to perform the assigned audit tasks. The Client and their representatives commits to provide DQS with accurate and complete information in a timely manner concerning all processes which may be significant to the certification. This relates in particular to the scope of a certification. Within the scope of certified management systems, all records relating to complaints and their corrective actions shall be presented to DQS upon request. When necessary, the participation of observers in the audit shall be permitted.

3.3 Notification of Changes

The manufacturer informs DQS MED immediately in writing about planned substantial changes to:

- the approved quality management system or systems or to the product-range covered
- the approved design of a device
- the intended use of or claims made for the device
- any substance incorporated in or utilized for the manufacturing of a device and being subject to the specific procedures in case of:
 - o Devices incorporating a medicinal substance as an integral part thereof
 - o Devices manufactured utilizing, or incorporating, tissues or cells of human or animal origin, or
 - o their derivatives, that are non-viable or rendered non-viable, as an integral part thereof
 - o Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body
- and any other planned changes that may be relevant to the certification decision.

DQS MED may make a new offer to the manufacturer to check whether the changed quality management system still meets the requirements of the regulation after the proposed changes. DQS MED assesses the planned changes, informs the manufacturer of the decision and transmits the results of the evaluation. Approval of a substantial change to the quality management system or the range of products covered by it is given in the form of a supplement to the EU quality management certificate. The manufacturer must provisionally allocate the medical devices covered by the applied-for certification under the applicable regulation into device categories or generic device groups and must notify DQS MED about such allocation. DQS MED will decide at its own discretion whether such allocation is correct or whether a different allocation needs to be made. The manufacturer must provide DQS MED with all necessary information for such allocation and pledge its full cooperation.

The manufacturer notifies DQS MED about planned changes to the approved design dossier where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device.

The Client is obliged to inform DQS MED without delay of any changes, which may influence the certified management system or the certified products. This applies in particular to the legal, economic or organizational status or the ownership, organization and management, changes to the product or the production method, contact data and production facilities or sites and important changes to the quality management system, the purchase/ sale of all or a portion of the company, any change in ownership, major changes in operations, fundamental alterations in processes or the filing for bankruptcy or composition proceedings. In any of these cases, DQS will consult with Client and determine how the certificate may be maintained.

3.4 Independence of Auditing and Certification

Client is obliged to avoid anything that might compromise the independence of the employees

and auditors of DQS MED. This applies in particular to offers of consultancy, offers of employment, both salaried and subcontracted, to separate agreements about fees or other monetary rewards.

3.5 Right to reject Auditor

Prior to confirmation of the audit date, the Client is entitled to review and reject the auditor(s) assigned by DQS MED with proper justification in writing. In that case, DQS MED will assign a replacement for the rejected auditor. This applies to auditors in training/ qualification, too.

3.6 Confidentiality and Information Security

The documents provided to the Client by DQS MED, including the Marks and the DQS MED certification symbol, are protected by copyright. Client specifically acknowledges that all documents which are provided or made available by DQS MED for examination remain the property of DQS MED, and that they may be used only for the internal needs of Client and not made available to third parties or be used for purposes other than those agreed upon herein or in writing. Client is obliged to maintain strict confidentiality about any information revealed within the terms of this Agreement as well as of all knowledge of matters relating to DQS MED, its employees and auditors. This obligation also applies after termination of the contract. Client shall not use their certification in any manner that may discredit DQS MED, nor shall Client issue any statements regarding their certification that the certification administration may regard as being misleading or unjustified. Client similarly accepts this obligation on behalf of any vicarious agents and auxiliary persons. Client is permitted to forward the audit report in its entirety. The forwarding of extracts is not permitted.

3.7 Right to use Certificates and Marks

With a valid DQS MED certificate, the Client is entitled to use the certificate and respective certification marks for promotion purposes.

Authorized use of copyrighted DQS MED Certified Management System Mark and other Certification Marks (herein referred to as the "Marks") shall enhance confidence of customers in the Client's certified management system and the respective performance. These Marks are frequently used on company stationery, in brochures, the Internet, at exhibitions, on vehicles or in advertisements. The Marks are directly associated with the certified organization and its management system or products. Certificates and Marks may be used for promotion in accordance with the provisions of these Auditing and Certification Regulations. Such use is restricted to the scope and the period of validity of the certification. Marks may not be attached directly to a product or used in such a way as to give rise to the impression of being related to the conformity of a product with the standard or specification on which they are based. Section 5, Certificates and Marks, provides respective rules in detail. DQS MED is obliged to ensure correct use of certificate symbols.

3.8 Appeals and Complaints

Every Client of DQS MED has the right to have services performed within the agreed scope in such a way that all reasonable expectations and requirements are fulfilled. In case of non-fulfilment, the Client is entitled to file a complaint with the respective DQS Company. DQS MED will request information necessary for analysis and improvement.

In case of a difference of opinion with DQS MED auditors or a specific certification decision, the Client has the right to submit an appeal to the responsible DQS Company.

If a solution cannot be worked out directly with the individuals concerned, Client may make a written appeal for resolution to the Top Management of the contracted DQS Company.

4. Rights and Obligations of DQS MED

4.1 Management System Audits

DQS MED verifies the conformity and effectiveness of Client's certified management system by

performing regular audits in accordance with DIN EN ISO / IEC 17021-1:2015 (at the moment within 12 months). For these audit purposes DQS MED has the right to access Client's facilities within the framework of planned audits as well as observe operations, inspect processes, products and services, interview employees and representatives, review documents and pertinent records, and to collect information using other audit techniques and methods.

DQS MED is authorized to carry out short-notice audits and unannounced audits at the certificate holder's expense.

Unannounced audits can also be carried out without a special reason and do not replace a regular audit.

Unannounced audits may also be conducted on the premises of critical subcontractors and/or a crucial supplier.

The certificate holder must contractually ensure with its critical subcontractors and/or crucial suppliers along the supply chain that DQS MED has access to the premises of the respective companies at all times for audit purposes.

As part of such unannounced audits, but also as part of surveillance audits, DQS MED may inspect and test recently produced suitable sample(s), preferably from the continuous manufacturing process, at the certificate holder's expense.

Transport, insurance, logistics, customs clearance, etc. of the sample(s) for DQS MED should be organized by and at the expense of the certificate holder.

If visas are required for unannounced audits, the certificate holder will provide DQS MED with invitations to visit critical subcontractors or important customers (invitations on which the signature and visit date have been left blank will be filled in subsequently by DQS MED).

4.2 Accreditation and Authorization

DQS MED is authorized by various accreditation bodies and other Government and Non-Government Authorities to issue audit reports and certificates according to various standards and specifications. This includes the obligation to allow employees or auxiliary persons of these bodies to participate in audits. According to the applicable accreditation and authorization rules, DQS MED allows these individuals access to both its own documents and Client-related data, subject to the confidentiality requirements set forth herein. In addition, whenever individual standards or specifications explicitly require, Client-related data and audit results are passed on to these bodies. By accepting these Auditing and Certification Regulations the Client consents to the applicable accreditation and authorization requirements, including all of the following. DQS MED is entitled to assign specific auditing and certification tasks to other DQS Companies holding the required accreditations or authorizations. Whenever certificates are issued by a DQS Company other than the Client's contractual DQS partner, all relevant rights and obligations herein apply equally to both the accredited and the certifying DQS Company.

4.3 Assignment of Auditors

The assignment of competent auditors is the sole responsibility of DQS MED. DQS MED agrees to use only auditors who are qualified for the task on the basis of their technical qualification, their experience and their personal abilities. Auditors shall be authorized for the required standard(s) or specification(s) and will have appropriate experience in Client's area of operation as well as in management and auditing. In many cases DQS MED may assign an audit team, comprised of two or more auditors, to a specific auditing or certification process.

On request, DQS MED will submit a short CV of the selected auditor to the Client.

Should an auditor become unavailable before or during the audit, DQS MED will strive to provide a suitable replacement, if feasible.

4.4 Scheduling Audits

DQS MED has the right to schedule audits and certifications of the Client's management system. Audits shall be scheduled at the mutual convenience of both parties within the timeframes mandated by the applicable requirements. Audit dates shall be agreed upon in writing. Once confirmed, such audit dates are binding. Specific contractual agreements may include provisions for compensation for cancelling or postponing confirmed audits.

4.5 Issuance of certificate

DQS MED shall issue a Certificate (herein referred to as "Certificate") to Client upon Client's fulfilment of all certification requirements and contractual obligations.

The certification decision is the sole responsibility of the accredited and issuing DQS group company, based on the auditor's recommendation for issue and all audit results, as recorded in the audit report. DQS MED certificates are valid for a limited period of time, usually a maximum of three years, commencing from the date of issuance.

4.6 Confidentiality and Data Protection

DQS MED commits itself to protect the confidentiality of all confidential information of Client that is not publicly available and that is made available to DQS MED in the context of its activities on Client's premises, whether this information relates to internal matters of Client or to its business relations. This also applies to the verbal and written results of the audit. DQS MED will disclose confidential information to third parties only with the written authorization of Client, unless explicitly provided otherwise in these Auditing and Certification Regulations. When statutory provisions require, or contractual obligations permit, disclosure of confidential information, DQS MED shall notify the Client or the person concerned about it, unless prohibited by law. DQS MED retains records associated with audits for a minimum of two certification cycles (usually six years). These commitments also apply after termination of the contract.

4.7 Publication

DQS MED is entitled to maintain and publish a register of all Clients holding a current DQS MED certification. This publication contains the name and address of the certified organization as well as the scope and reference standard/specification and certification status. Client hereby consents to the publication of such information hereunder. The publication follows the legal requirements and is up to the discretion of DQS MED.

4.8 Electronic Communication

Notwithstanding the foregoing, Client hereby authorizes DQS MED to transmit unencrypted confidential information and other information through the Internet or a public network to e-mail addresses or other locations provided by Client. Client acknowledges that DQS cannot guarantee the privacy and confidentiality of such transmissions. Client agrees that DQS' transmission of confidential information via the Internet or other public network shall not be a breach of any confidentiality obligation under these Auditing and Certification Regulations and that DQS MED shall not be liable for any damages resulting from such transmissions, provided that such confidential information is handled with the same degree of care as DQS MED handles its confidential information.

If Client hyperlinks to DQS MED web site, Client agrees:

- (i) the information contained on DQS' web site belongs to DQS MED;
- (ii) the linking web site will transfer the user directly to DQS MED web site as posted without imposing any frames, browser windows or third-party content; and
- (iii) the linking web site may not state or imply that Client or its products or services are endorsed by DQS MED.

5. Certificates and Marks

5.1 Issuance and use

DQS MED issues certificates confirming the conformity of the Client's management system to selected national and international standards as well as to recognized industry- or customer-specific requirements, when the Client has demonstrated in an audit that all applicable requirements have been fulfilled. Management system certificates do not confirm compliance with legal requirements. The Client is entitled to use the certificate and the related certification marks to promote confidence with business partners. Upon issuance of a Certificate, an ongoing surveillance service will be established to ensure that conformity of the management system is maintained continuously. The establishment and maintenance of certification is contingent upon the execution of the auditing and certification agreement and the continued adherence to its terms and conditions by the Client.

Client agrees to cooperate with DQS MED in ascertaining the facts if it is reported that Client's management system, processes, goods or services are not in conformance with regulatory, statutory, certification or other applicable requirements, including sharing such information as Client acquires regarding the reported non-conformance, and to take and report to DQS MED on any corrective action necessary.

Client agrees that the surveillance service, such as advancement audits, and any special audits conducted are designed to serve only as a check on the means the Client exercises to determine conformance of its management system with certification requirements, and that Client is in no way relieved of its responsibility for its management system, processes, goods and services within the scope of certification.

Certificates and Certification Marks may not be transferred to successors in title or other organizations. After a certification has expired or has been suspended, withdrawn or annulled, Client must desist from any promotion or other use of the certification. Client agrees to return the certificate following expiration, withdrawal or annulment. The right of retention is specifically excluded. Further information on the Marks is available on the website of DQS MED (www.dqs-med.de).

5.2 Non-issuance of Certificates

DQS MED can only issue Certificates if all requirements of the selected standard(s), specifications and contracts have been fulfilled following the certification (initial/re-certification). In case of non-fulfilment, the auditor documents the shortcomings in a nonconformity report and/or otherwise identifies the restraints which must be complied with in order for a certificate to be issued.

All non-conformances or restraints shall be eliminated prior to the issuance of a DQS MED certificate. If necessary, DQS MED will repeat the audit partially or in full. If the non-conformances have not been eliminated or if the prerequisites for the granting of a certificate have not been achieved even after follow-up audits, the certification procedure will be concluded by the issuance of a report without a certificate.

5.3 Suspension, Withdrawal and Annulment of a Certificate

5.3.1 Suspension

DQS MED is entitled to suspend temporarily a Certificate if Client violates certification, contractual or financial obligations towards DQS MED, including but not limited to:

- Corrective actions to the management system have not been demonstrably and effectively implemented within the agreed-upon time frame

-
- The schedule of audits suggested by DQS MED for audit(s) necessary for the maintenance of the certification have not been complied with and the prescribed deadline in accordance with 4.1 since the previous audit has thereby been exceeded
 - DQS MED has not been informed in a timely manner about planned changes to the management system and other changes which affect the system's conformity with the standard or specification which forms the basis for the certification
 - A DQS MED certificate, an IQNet certificate or a certification symbol has been used in a misleading or unauthorized manner
 - Due payments for auditing and certification services have not been made in time, following at least one written reminder.

DQS MED will notify Client of a proposed suspension in writing. If the reasons for the proposed suspension are not eliminated within two weeks, DQS MED will inform Client in writing of the suspension of the Certificate stating the reasons as well as the corrective actions necessary for the certification to be reinstated. Certificates are suspended for a restricted period (usually a maximum of 90 days). If the required measures have been implemented demonstrably and effectively by the established deadline, the suspension of the Certificate is cancelled. If the required measures have not been implemented within the established deadline, DQS MED may withdraw the Certificate as set forth below.

5.3.2 Withdrawal

DQS MED is entitled to withdraw Certificates or to declare them invalid upon written notice to Client if:

- The suspension period of the Certificate has been exceeded
- The conformity of the management system with the standard or specification on which it is based is not ensured or Client is not willing or able to eliminate nonconformities
- Client continues to use the certification for promotion following the suspension of the Certificate
- Client uses the certification in such a way as to undermine the reputation of the certification body or DQS MED
- The preconditions which led to issuing the Certificate no longer apply
- Client files any voluntary or involuntary petition for bankruptcy
- Client effectively terminates its contractual relationship with DQS MED
- Due payments for auditing and certification services have not been made in time, following at least one written reminder.

5.3.3 Annulment

DQS MED is entitled to annul Certificates, or retroactively declare them invalid, if:

- It subsequently turns out that the preconditions required for issuance of the certificate had not in fact been fulfilled,
- Client has compromised the certification procedure, so that the objectivity, neutrality or independence of the audit results are in question.

6. Sector-specific requirements

In addition to the provisions stipulated above, specific technical requirements of individual standards or specifications and their complementary interpretations, collectively known as “Program Requirements” are applicable as follows:

DQS MED Programs:

General Business Conditions (GBC) of DQS Medizinprodukte GmbH

Supplement to the GBC of DQS Medizinprodukte GmbH applicable for auditing and certification under MDD 93/42/EEC

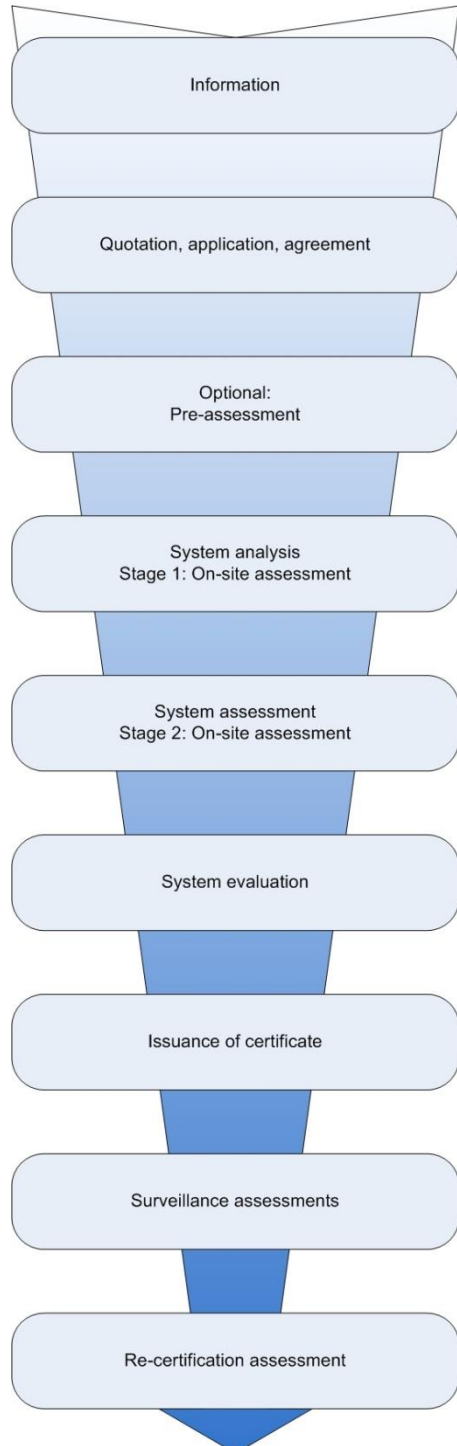
Supplement to the GBC of DQS Medizinprodukte GmbH applicable for auditing and certification under Medical Device Single Audit Program (MDSAP)

Supplement to the GBC of DQS Medizinprodukte GmbH applicable for auditing and certification under MDR

For all DQS MED Programs the Sector-specific requirements apply before the General Business Conditions of DQS Medizinprodukte GmbH and the DQS Auditing and Certification Regulations.

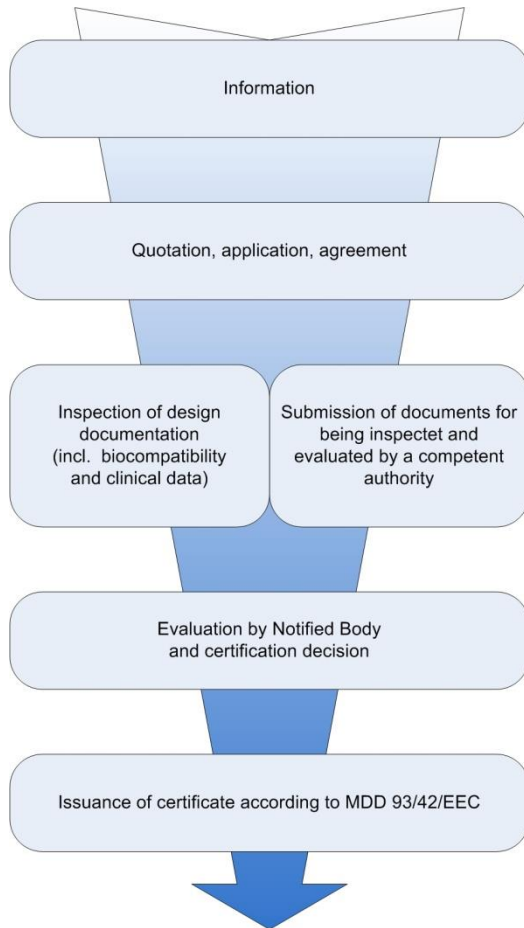
DQS Certification Process for Management Systems

From offer to certificate – System certification



- An exchange of information about objectives and benefits of the certification, about the certification process and the scope of your management system. At the same time your individual concerns and needs will be recorded.
- You will receive a detailed offer that clearly lists all of the scheduled steps of the assessment process. Information on the time schedule, the extent, and the cost of the assessment will be specified in a transparent manner.
- In order to provide certainty for the certification, selected areas or processes may be evaluated during an advance audit on site.
- The assessment procedure itself begins with review and evaluation of system documentation and a first look at goals and results of management reviews or internal audits. During this process, it will be determined whether your management system is already sufficiently developed and ready for certification. The auditor will explain the findings and coordinate the remainder of the time schedule and the contents of the on-site assessment with you.
- Your management system will be assessed and evaluated comprehensively at the place of supply of services. The objective is to determine system compliance to the requirements and, also to define potential for improvement. The auditor of the audit team will evaluate the effectiveness of all functional areas as well as all management system processes, based upon inspections, interviews, and review of pertinent records among others. The audit result and findings will be presented during the final meeting. Action plans will be agreed upon as necessary.
- You will receive a written report on the results of the assessment. DQS will evaluate the results and decide independently on issuance of the certificate.
- At least once per annum there will be on site assessment of the critical components of the management system. Improvement potential will be identified, with a focus on continual improvement and sustained effectiveness.
- Before the certification expires, a new comprehensive assessment and evaluation of the system is performed regarding its compliance with the standard' requirements and improvement potentials are being extrapolated.
- New issuance of certificate

From offer to certificate according to MDD 93/42/EEC



- Change of information regarding objectives and benefits of a design examination and regarding the certification process.
- You get a detailed quotation in which the planned steps of the assessment process are described clearly. The timely course of action, the amount of our services and costs are fixed transparently.
- With the assessment and evaluation of the design examination documentation, the actual assessment procedure starts. Thereby it is established if your design examination documentation fulfills the based upon requirements and is certifiable.
- With devices with medicinal products contents in terms of the Directive 2001/83/EC and with devices manufactured utilizing tissues of animal origin according to Directive 2003/32/EC, we initiate a consultation procedure with a competent authority.
- The lead assessor provides the results of the clinical and technical assessor summarized in one report. In the report you get the records and results of the assessment, if need be action plans are agreed upon. DQS evaluates the results and decides independently on the issuance of the certificate.
- Before expiration of the certification, a new comprehensive assessment and evaluation of the design examination documentation is performed. In the context of the design examination, usually the management system is also being assessed, in order to check and evaluate the documented processes.