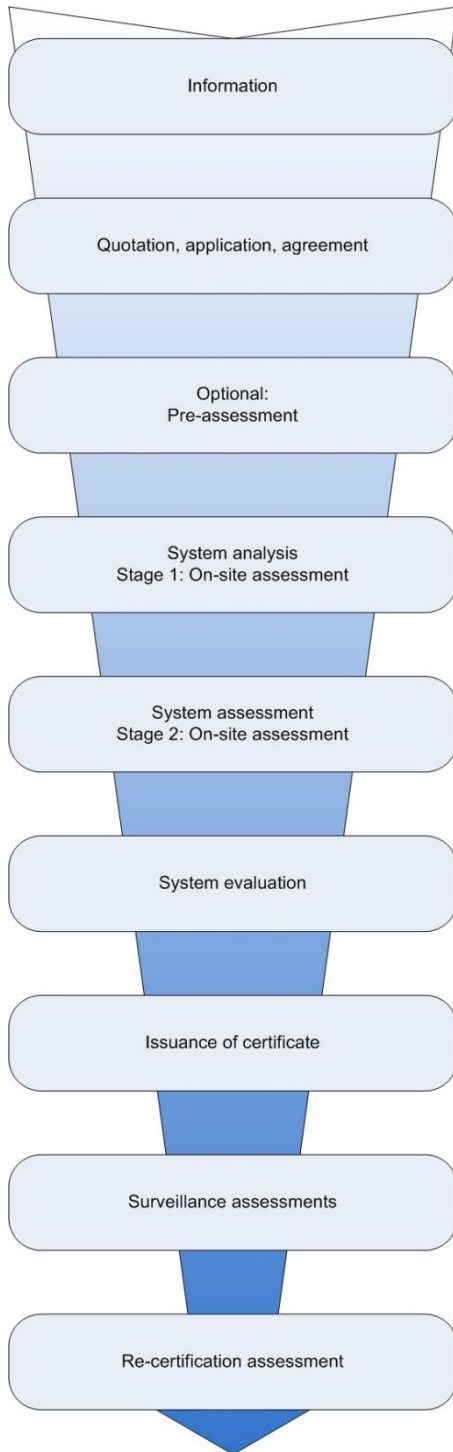


Building trust and keeping promises

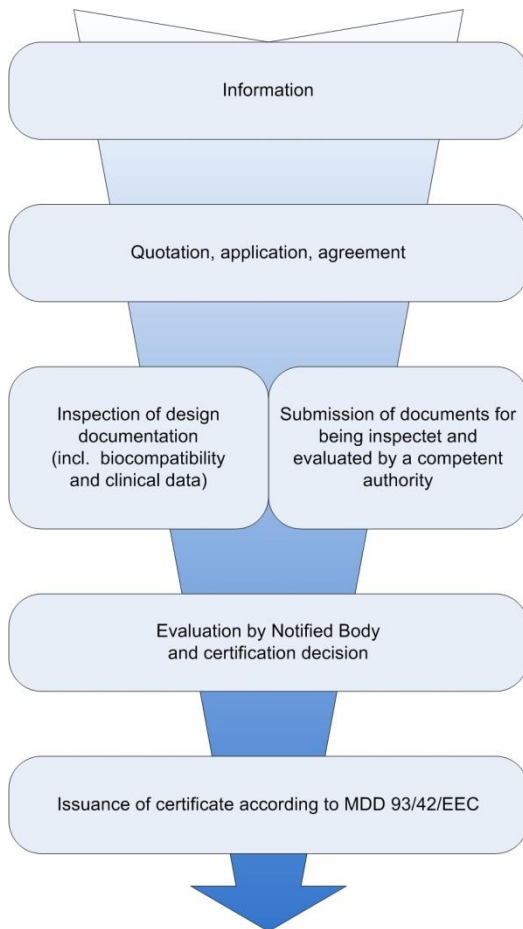
The assessment of a management system by an independent third party has many advantages extending beyond the simple confirmation of the conformity of a system with the requirements of a standard. Our customers place particular value on the improvement potential contributed by the technical competence and practical experience of DQS auditors. A DQS assessment supports your efforts to focus the entire organization towards success – so your customers will continue to regard you as a valuable and reliable partner in the future.

Your way to the 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's/rules' 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 evaluated 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.

Assessment services and Prices

All fees stipulated are subject to incidental charges and the current statutory level of value added tax.

System analysis / System assessment / Project planning / Follow-up assessment / Benchmarking

	per assessor / day
- Planning meeting on-site with the customer (per participant of DQS MED and per hour or part thereof).....	EUR 180,-
- Assessment of quality management systems	
acc. to ISO 9001:2008	EUR 1.290,-
acc. to ISO 9001:2015	EUR 1.350,-
acc. to ISO 13485 or ISO 15378	EUR 1.350,-
- Quality assurance systems acc. MDD 93/42/EEC, CMDCAS	EUR 1.425,-
- MDSAP	EUR 1.500,-
- Combined / integrated management systems (without MDSAP)	EUR 1.425,-
- Examination of tech. documentation acc. MDD 93/42/EEC annex II section 4 (at least EUR 10.000,-)	EUR 1.425,-
incl. consultation procedure with competent authority	T & M basis
- Change notification and technical file review incl. report	EUR 1.425,-

System evaluation

- Written report	
acc. to ISO 9001:2008	EUR 1.290,-
acc. to ISO 9001:2015	EUR 1.350,-
acc. to ISO 13485* and/or ISO 15378* (*also with ISO 9001:2008)	EUR 1.350,-
acc. to MDD 93/42/EEC and /or CMDCAS (also in connection with above mentioned standards, except ISO 9001:2015)	EUR 1.425,-
acc. MDSAP	EUR 1.500,-
- combined / integrated standards (at least 3 Standards, except ISO 9001:2015 and/or MDSAP)	EUR 1.490,-
- Written report for follow-up assessment	T & M basis
- Written report for advancement assessments	
acc. to ISO 9001:2008	EUR 500,-
acc. to ISO 9001:2015	EUR 500,-
acc. to ISO 15378* (*also with ISO 9001:2008)	EUR 500,-
- Preparation and post-processing of unannounced audit	EUR 750,-
- Written report for Taiwan Technical Cooperation Program (TCP)	EUR 500,-
- Written report QVH - Quality Seal	EUR 500,-

Certificates by DQS Medizinprodukte GmbH

- Issuance of a certificate – in German and one additional language*), as well as use and publication during its period of validity	
- for the first standard or regulation	
acc. to ISO 9001 (and no further standard)	EUR 460,- / p.a.
acc. to ISO 13485, MDD 93/42/EEC or ISO 15378	EUR 970,- / p.a.
- for ISO 13485 under CMDCAS	EUR 970,- / p.a.
- for MDSAP	EUR 1.000,- / p.a.
- for each additional standard or specification	EUR 450,- / p.a.
- Issuance of TCP certificate and a Taiwan Cover Letter	EUR 1.500,- / p.a.
- Issuance of certificate in additional European languages* each	EUR 120,- / per changed page
- Excerpt certificates and changes to certificate each	EUR 120,- / per changed page
- Surcharge for other languages not listed	T & M basis
- Publication on the DQS MED website	free of charge
- Personal hand over of certificate by a DQS MED representative (by request)	T & M basis
- Imprint of the company logo for maximum 2 language versions	EUR 90,00
- Imprint per logo and logo size for each additional language	EUR 35,00
- Reprints of certificates (DIN A 4) with or without company logo	Basic Rate per Registration No. EUR 15,00
- each additional page	EUR 5,00
- Notarization of a certificate	EUR 220,00
- Certificate apostille	EUR 280,00
- Printout and sending of audit report by (traditional) mail	EUR 10,00
- Cancellation and termination of upcoming assessments	EUR 375,00
- Cancellation and termination of standards of existing certificates / standards	EUR 375,00

* Certificate languages: European languages for DQS certificates are German, English, French, Italian, Spanish, Polish, Portuguese and Turkish.

Database entries, registrations, other	
- DIMDI notification in the course of initial or re-certification.....	free of charge
In the course of a reportable change each	EUR 60,-
DQS Club for the exchange of experiences	
- three club meetings per year and participant.....	EUR 350,-
Translation costs for audit reports / reports of technical documentation	
- Flat rate for up to 10 pages	EUR 500,-
For each additional page	EUR 20,-

Using the DQS MED certificate symbol

With a DQS certificate you are announcing your determination to supply superior performance. We are delighted by our customers using our copyrighted DQS certificate symbol, because it is a confirmation of the trust placed in us, a sign of their loyalty and satisfaction with the quality of our services, whether it is used on company stationery or in brochures, on the Internet, at exhibitions, on vehicles or in advertisements. The certificate symbol is directly associated with the certified organization and its management system. Further information and downloads are available on the Internet at www.dqs-medizinprodukte.de.

Calculation of effort required

Please request an individual offer:

The assessment of each organization will be planned individually. Important factors are, among others, variety of products (goods and services), complexity of work processes/procedures, special product characteristics, environmentally relevant facilities, statutory requirements, company size, number of employees, degree of automation, organizational structures and distribution of sites. The procedures are based upon the currently valid global accreditation and authorization requirements. Following determination of the effort required, the assessment days will be agreed upon in writing with the customer. Assessment days comprise eight hours per day. Assessments and follow-up assessments may be conducted on site or by document review, subject to their placement in the assessment.

Incidental costs

Travel expenses: by car: € 0,69 / km, by rail: 1st class, by plane: Economy Class (Business Class only in case Economy is not available). All expenses incurred will be charged at cost.

Overnight stays: We request the customer to either nominate or reserve on behalf of the assessor(s) an appropriate facility nearby. We suggest the customer settle the overnight costs directly with the hotel.

Travel time: The travel time fee will only be charged for trips with duration of 2 hours or longer in one direction. A fee of EUR 100,- will be charged per hour or part thereof. The maximum settlement for domestic trips amounts to 8 hours per one way. Trips within a border control union – e.g. within the Schengen Agreement member states – are considered as domestic trips.

Other expenses: No other expenses will be charged.

Project planning

The planning of assessments involving multiple sites, for groups of companies or trusts will be conducted during an annual project meeting with the customer on site. For planning, the Lead Auditor assigned will take into account changes and customer requests, as well as previous audit results. Other auditors may participate in the project meeting as necessary.