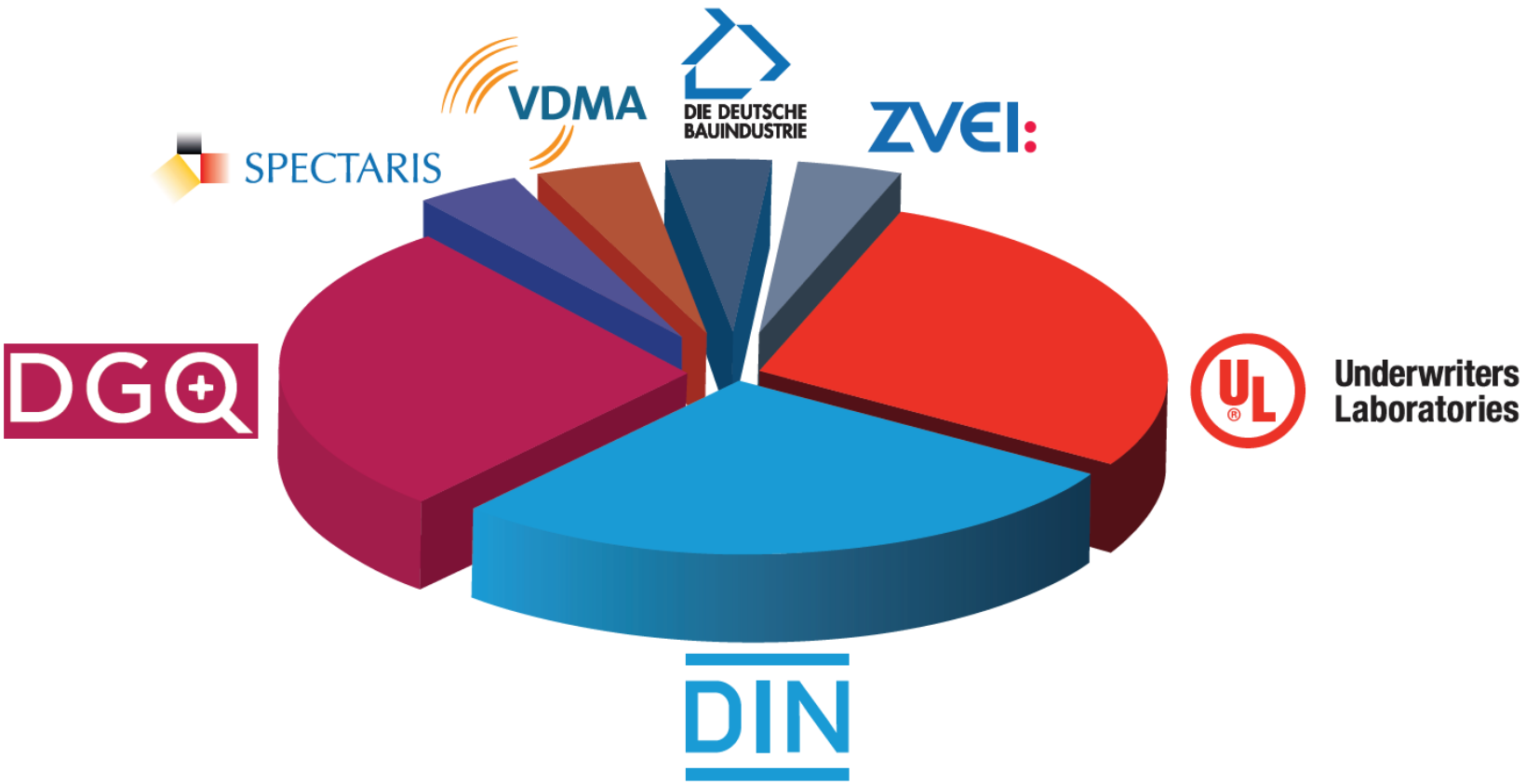
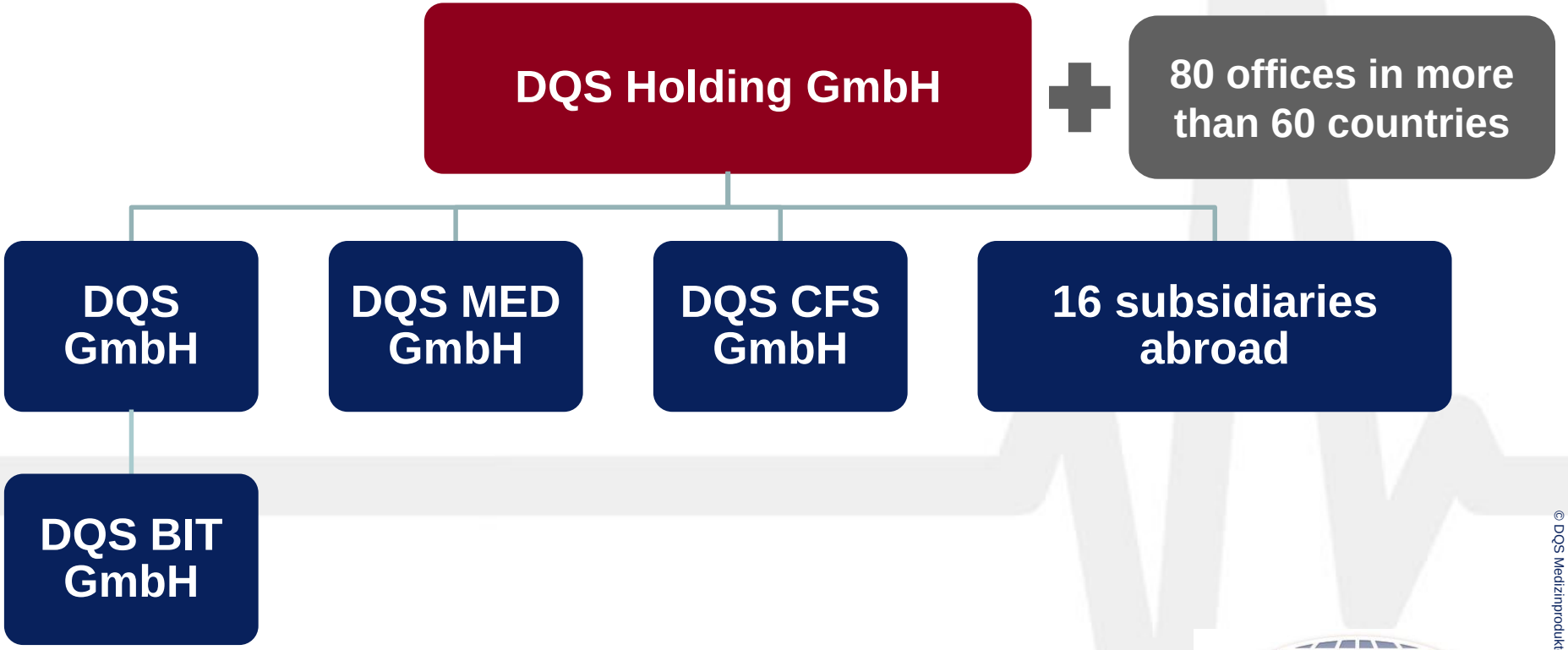
Member of the DQS group

Shareholder of the DQS Holding GmbH



Consolidated companies of the DQS group



DQS group worldwide

2.500
Auditors and experts

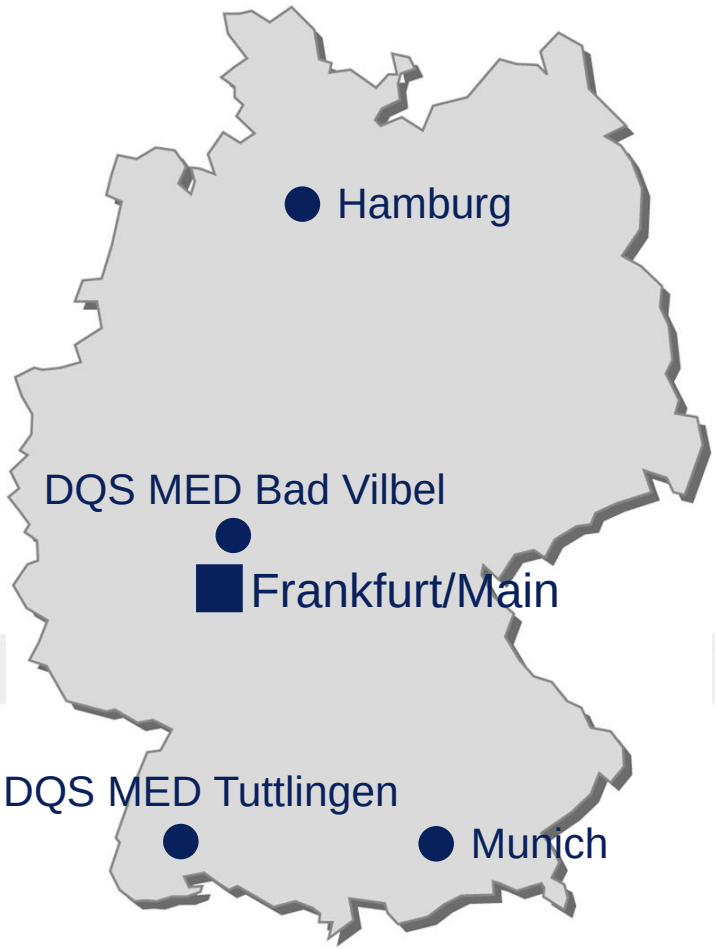
58.000
Certified locations in over
130
countries

105.000
Audit days per year

80
Offices in more than
60
countries

IQNet member
with 36 certification partners

Sites of the DQS group in Germany



1985
DQS GmbH – first certification company accredited in Germany


TGA - Trägergemeinschaft für Akkreditierung - German Association for Accreditation GmbH

Member of the Multi Lateral Agreement of EA and IAF represented in the

Deutschen AkkreditierungsRat

Accreditation

The TGA - Trägergemeinschaft für Akkreditierung - German Association for Accreditation GmbH herewith confirms that the certification body

DQS GmbH Deutsche Gesellschaft zur Zertifizierung von Managementsystemen
August-Schanz-Strasse 21
60433 FRANKFURT AM MAIN

carry out the certification of
andard within the scopes

(Dr. Thomas Facklam)
Head of the accreditation body

See notes overleaf

DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main, Germany

Milestones

- Juli 2008: Foundation of DQS Medizinprodukte GmbH (100% shareholder DQS Holding GmbH)
  - *In 1995, established as the DQS center of excellence for medical devices and designated as an notified body for directive 93/42/EEC*
- Strategic targets: Strengthen the market presence, increase in market share, expansion in international market
- Facts & Figures 2021:

Revenue	No. of employees	Auditors
~ 18 Mio.	~ 100	~ 250

- More than 1600 customers

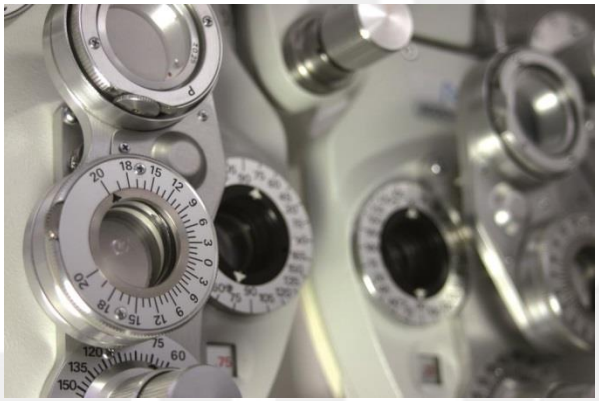
Some references

Accreditations and designations

- **German accreditation body** (DAkkS)
  - ISO 9001 (QM),
  - ISO 13485 (medical devices – QM – requirements for regulatory purposes)
  - ISO 15378 (primary packaging material for medicinal products)
- **Standards Council of Canada/ Health Canada** (SCC)
  - ISO 13485 (medical devices – QM – requirements for regulatory purposes)
- **MDSAP- consortium**
  - Medical Device Single Audit Program (MDSAP)
- **Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten** (ZLG)
  - European directive 93/42/EWG (MDD) for the risk classes Im/Is, IIa/IIb, III
  - Notified under European regulation 2017/745 MDR on August, 8th, 2020

Further services

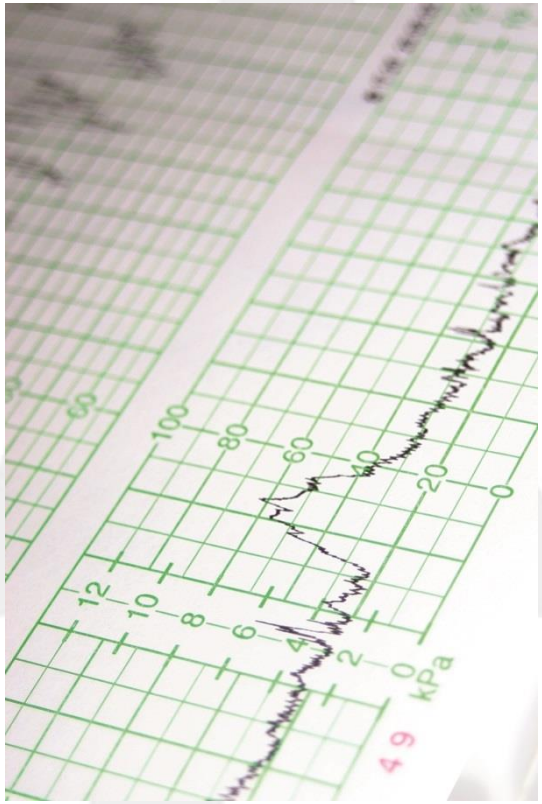
- certifications and approvals in close cooperation with the DQS Group
- customized assessments
- sampling and group Certification
- seminars, workshops
- DQS-MED ERFA-Club medical devices



Customer Survey

- All things considered, how satisfied are you with the planning, implementation and reporting of the audit?

Note 2,0 (grade)

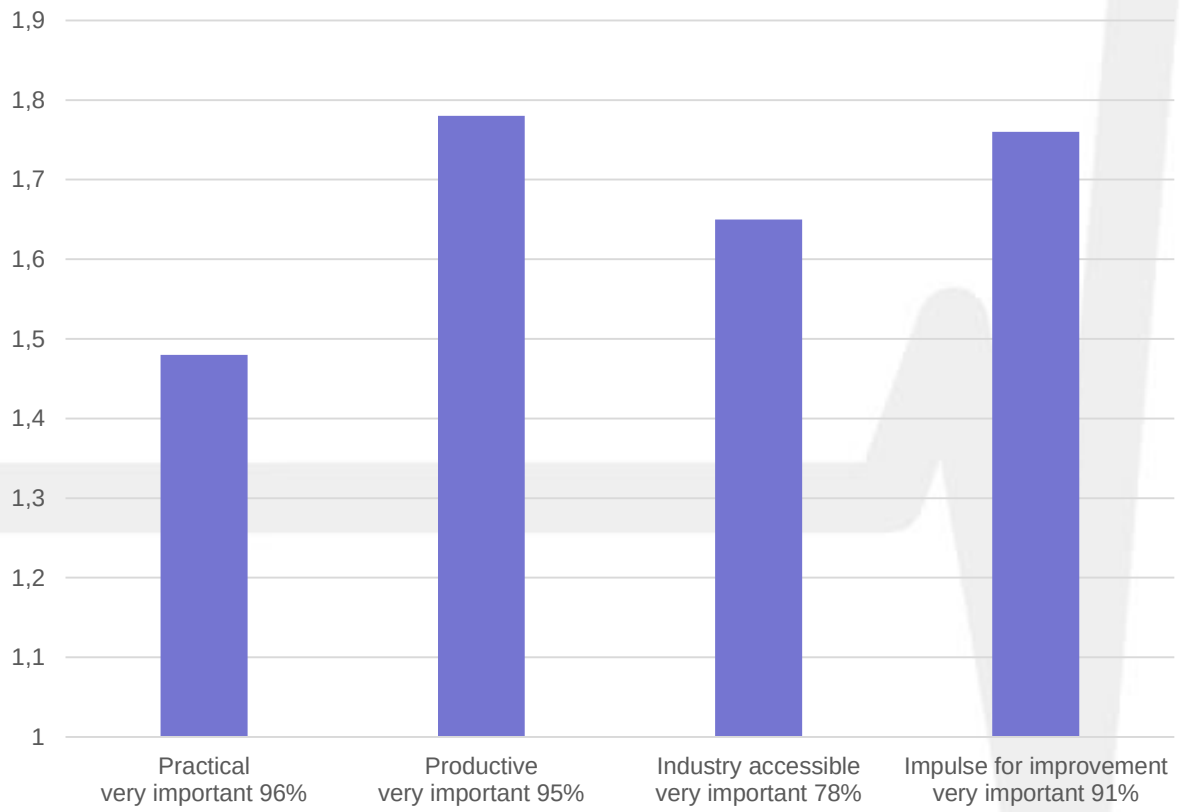


- How satisfied are you with the meaningfulness of our reports?

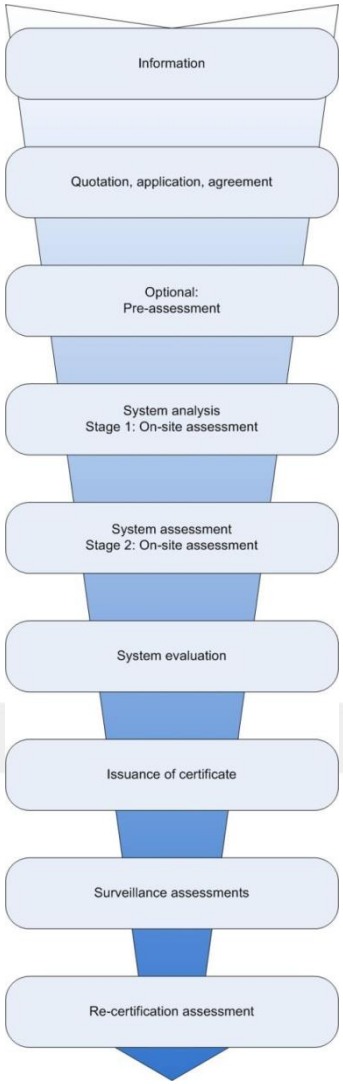
Note 2,0 (grade)

Customer Survey

- How would you rate the quality of our audits?
  (grade)

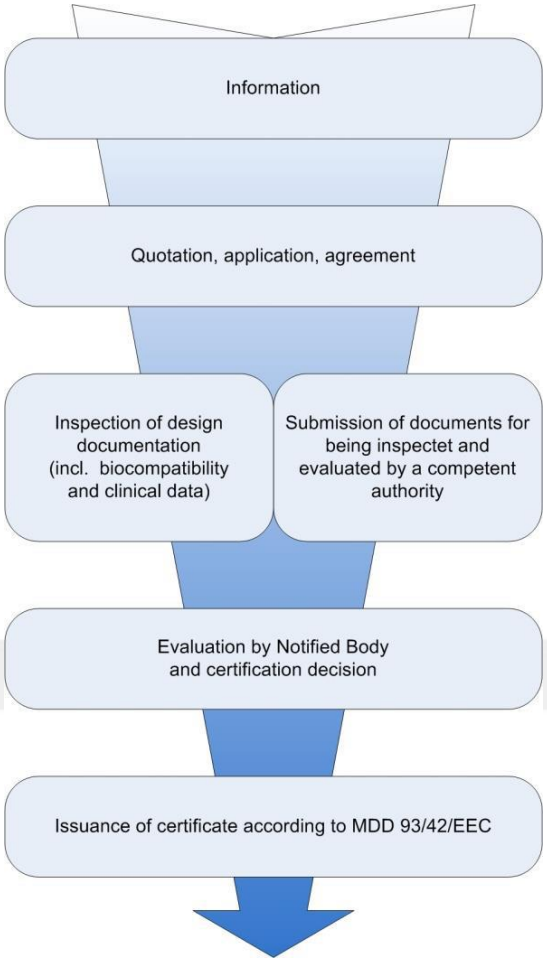


Certification process ISO13485/ ISO9001/ ISO15378/ MDSAP



- 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 deter-mine 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 standards/rules requirements and improvement potentials are being extrapolated.
- New issuance of certificate

Certification process Directive 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.

Certification process according to MDR (EUR) VO 2017/745 Part 1

INFORMATIONEN

Public Information

For information regarding our services, please visit www.dqs-med.de or contact us at any of our events. Naturally, you can also contact your customer service representative or our sales staff via email: sales@dqs-med.de.

Contacting DQS-MED

To provide you with our services, we require a description of your intended certification project, as well as some product-related information. Essential are here, above all, the intended use and the respective risk classification of your products. Please send us the above-mentioned required information about your company using the DQS MED basic data template.

ESTIMATE OF COSTS AND APPLICATION FOR CERTIFICATION

Pre-Evaluation of your Application

You will receive an estimate of costs, also specifying the estimated efforts for audit and Technical File Review, based on the information provided and documents submitted by you. This package will also include the application forms.

Certification process according to MDR (EUR) VO 2017/745 Part 2

Application

It may be necessary to provide additional information for clarification.

To accept the estimate of costs, please sign and subsequently submit the completed application form.

Important note: As outlined in the application form, your conformity assessment procedure according to VO (EU) 2017/745 will start with receipt of your completed application form. The application itself does not guarantee certification. Please be aware of our reporting obligations stated in our general terms and conditions.

Application review

As a first step, your application and the information you provided are checked and the result is documented.

Your application documents will be reviewed in a documented manner.

If there are any changes to the estimated costs during the application review, you will receive an updated estimate of costs from us.

Only with the acceptance of the formal application MDR (form) by the body an effective contract for the conformity assessment procedure according to Regulation (EU) 2017/745 is concluded.

AUDIT

Detailed Planning of the Customer Procedure

Based on the information and documents submitted by you, we plan the audit program. This consists of the evaluation and auditing of the QM system (system level) and examination of technical documentation (product level).

Certification process according to MDR (EUR) VO 2017/745 Part 3

Technical File Review

First of all, the required review(s) of the technical file(s) take(s) place. The result of the review(s) is summarized in reports and used in the further course of the conformity assessment procedure. You will receive a copy of these reports.

Important note: During the course of the technical file review you will have the opportunity for corrections. However, in case of new applications, we must stop your conformity assessment procedure after the third rework failed. This will result in reporting obligations for us, according to VO (EU) 2017/745.

Stage 1

Now, the system analysis (stage 1) takes place. It consists of reviewing the QMS documentation and your described procedures.

The question which needs to be clarified:

Is your system ready for the next step?

The results of the system analysis will be summarized in a report and used in the further course of the conformity assessment procedure.

Naturally, you will receive a copy of this report as well.

Updating the Planning, Supplementing Audit Objectives

We combine the results of the technical file reviews and the system analysis (stage 1) and assess whether the system assessment, that follows in the next step, can be carried out as planned or any adjustments (e.g. to the audit content) need to be made.

Important note: We must stop your conformity assessment procedure, if, even at the third attempt, you fail to demonstrate sufficient readiness for the following system assessment. This will again result in reporting obligations for us, according to VO (EU) 2016/745.

Certification process according to MDR (EUR) VO 2017/745 Part 4

System Assessment

The system assessment (stage 2) always takes place at your premises, as known from other certification programs.
However, audits under VO (EU) 2017/745 will include some changes, such as the onsite verification of specifications from the technical files and, if applicable, with respective samples.

System Evaluation (Report)

The results of the system assessment (stage 2) will also be summarized in a report.
In case any non-conformities were identified during the audit, they are also part of this report.
The report will conclude with the assessors' recommendation for certification.

CERTIFICATION DECISION MAKING

Certification Decision Making

The results of the system assessment will now be checked by the reviewer, confirming or rejecting the assessors' certification recommendation. If questions remain open in the report, further rework may be required. In this case, we will get in touch with you.
Important note: In the case of new applications, we have to conclude the conformity assessment procedure negatively, after the third negative final review.
This will result in a reporting obligation for us, according to VO (EU) 2017/745.

Certification process according to MDR (EUR) VO 2017/745 Part 5

DQS MED stands for high quality, which we safeguard through extensive internal quality assurance procedures.

As such we installed an overriding Certification Decision Board, ensuring that certification decisions are adequate and that corresponding action is taken accordingly.

Certificate Issuance

Congratulations, your certification has been granted!

You will now receive your certificate and the system assessment report.

Why DQS Medizinprodukte GmbH?

- Operating in the areas of medical device approvals and certification of management system in the health care markets for 20 years.
- Commitment to impartiality and independence in the performance of certification activities
- Notified body for medical devices – notified by the German ZLG for the European Directive 93/42/EEC (MDD) and VO 2017/745 MDR
- Accredited for ISO 13485, ISO 9001, ISO 15378 and MDSAP
- Further certifications and approvals in close cooperation with the DQS Group including ISO 14001, BS OHSAS 18001, ISO 27001, ISO 50001, etc.
- Transparency of offers and service delivery
- Fast processing times and a strong customer orientation
- Commitment to the highest degree of professional integrity and the requisite competence in assessments and examinations