DQS Medizinprodukte GmbH

MEMBER OF THE DQS GROUP

DQS MED | 20.04.2023

Agenda

01 **DQS Medizinprodukte GmbH**

Member of the DQS group

02 **DQS Medizinprodukte GmbH**

Figures, data, facts

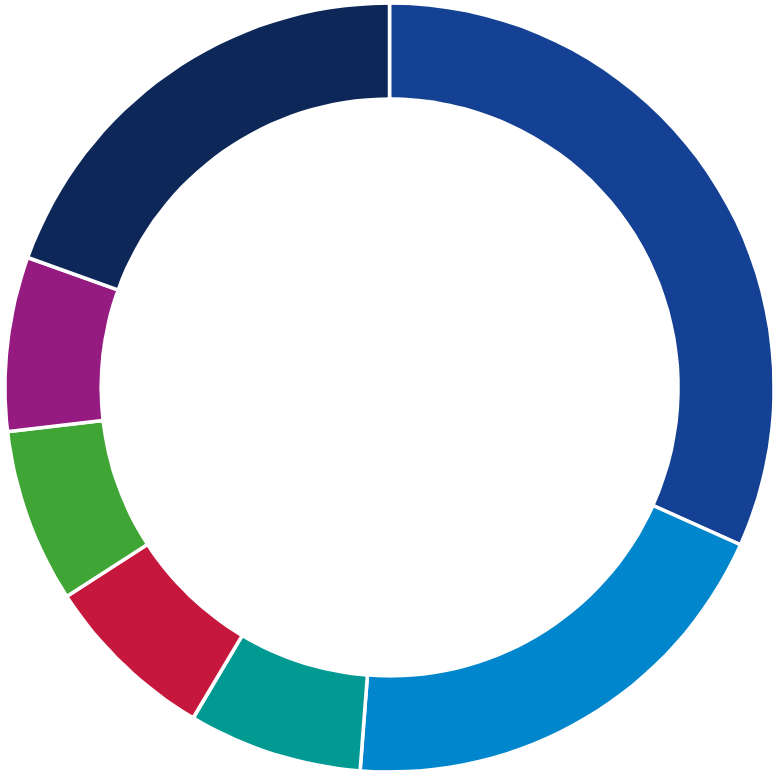
DQS Medizinprodukte GmbH

MEMBER OF THE DQS GROUP

01

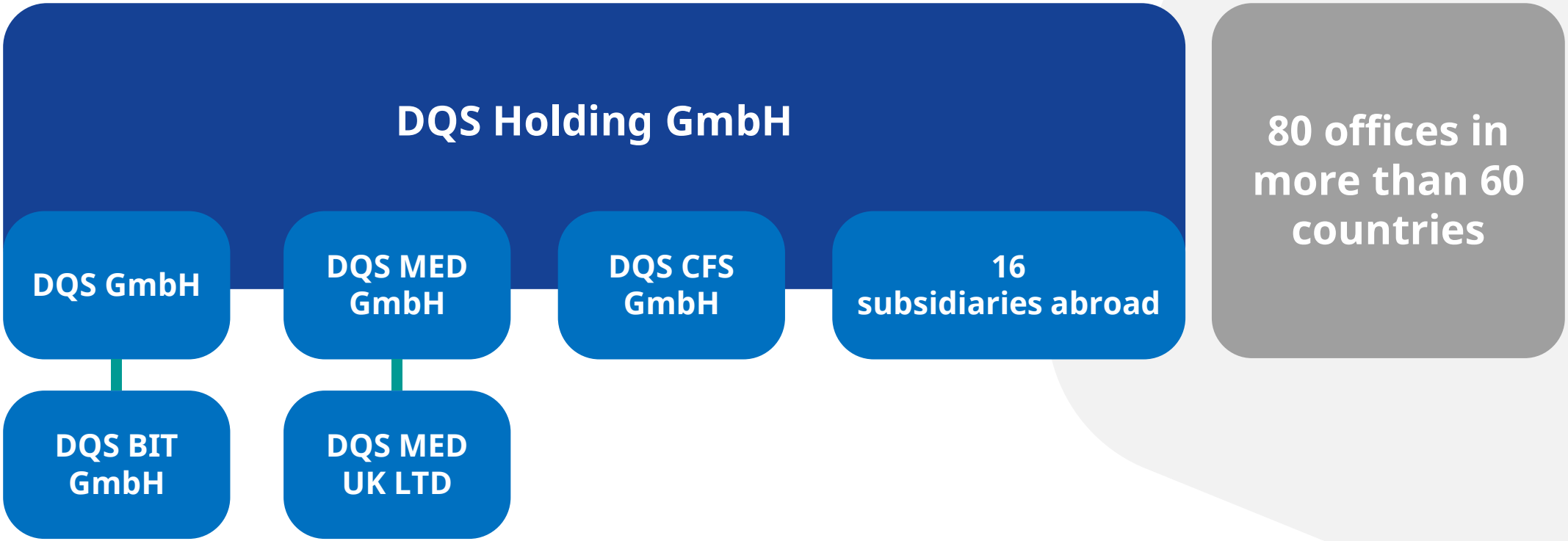
Shareholder

of the DQS Holding GmbH

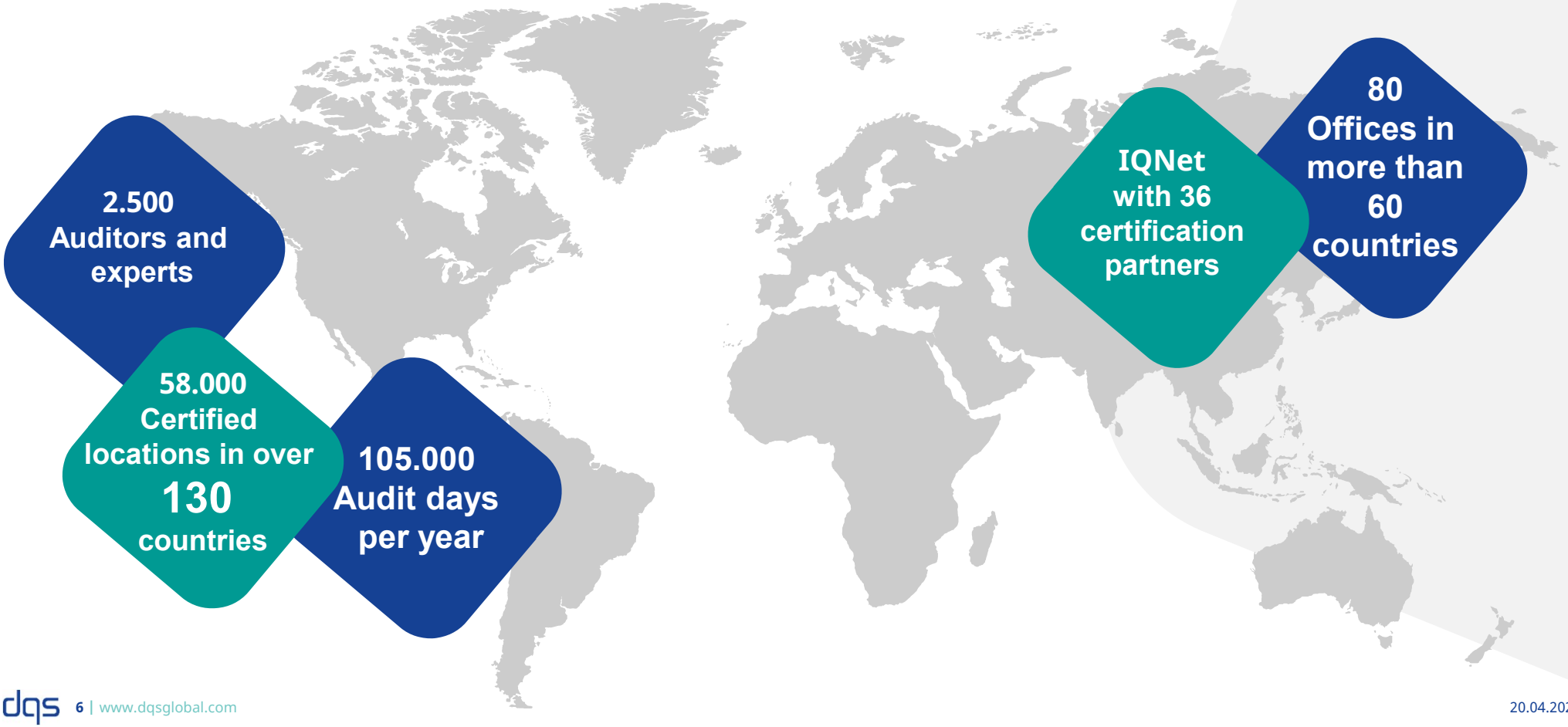


- Underwriter Laboratories
- DIN
- DGQ
- Spectaris
- VDMA
- Die Deutsche Bauindustrie
- ZVEI:

Consolidated companies
of the DQS group

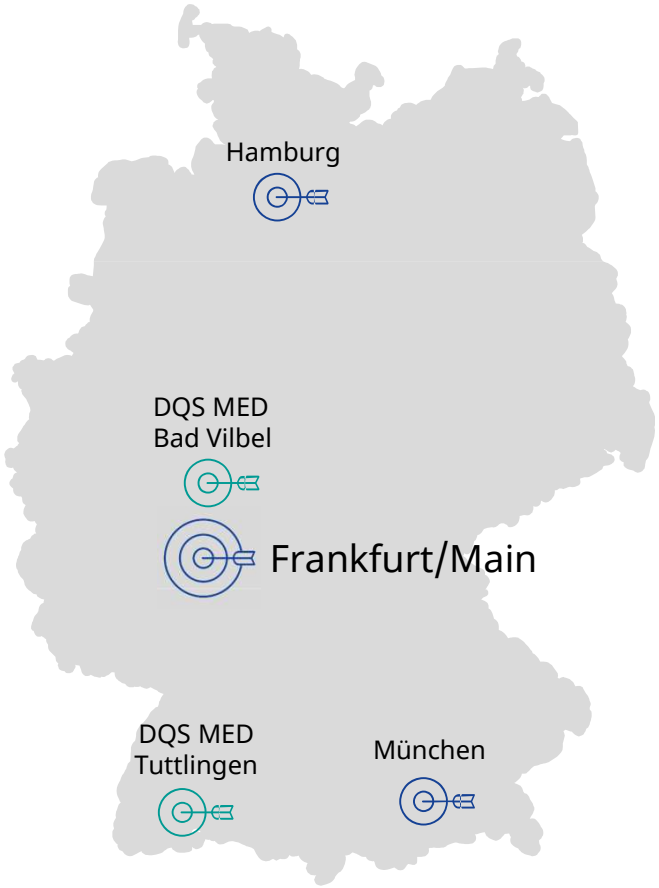


DQS group
worldwide



Sites of the DQS group

in Germany




TGA - Trägergemeinschaft für Akkreditierung -
German Association for Accreditation GmbH

Deutschen AkkreditierungsRat

Accreditation

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

1985 DQS GmbH

DQS GmbH – first certification company accredited in Germany

DQS Medizinprodukte GmbH

FIGURES, DATA, FACTS

02

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

~ 18 Mio

No. of employeees

~ 100

Auditors/ Experts

~ 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

Taiwan Food and Drug Administration (TFDA)

- TCP III

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

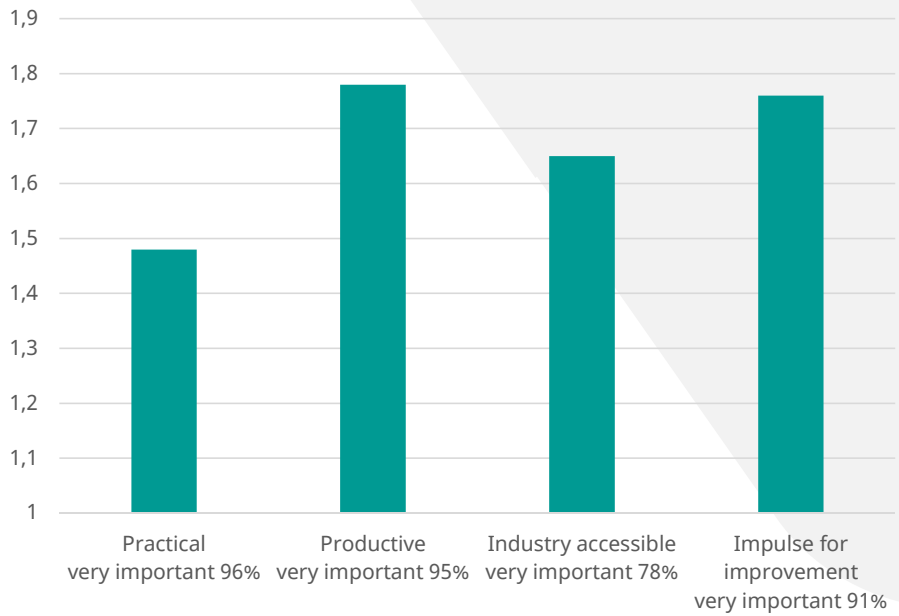
All things considered, how satisfied are you with the planning, implementation and reporting of the audit?

Note 2,0 (grade)

How satisfied are you with the meaningfulness of our reports?

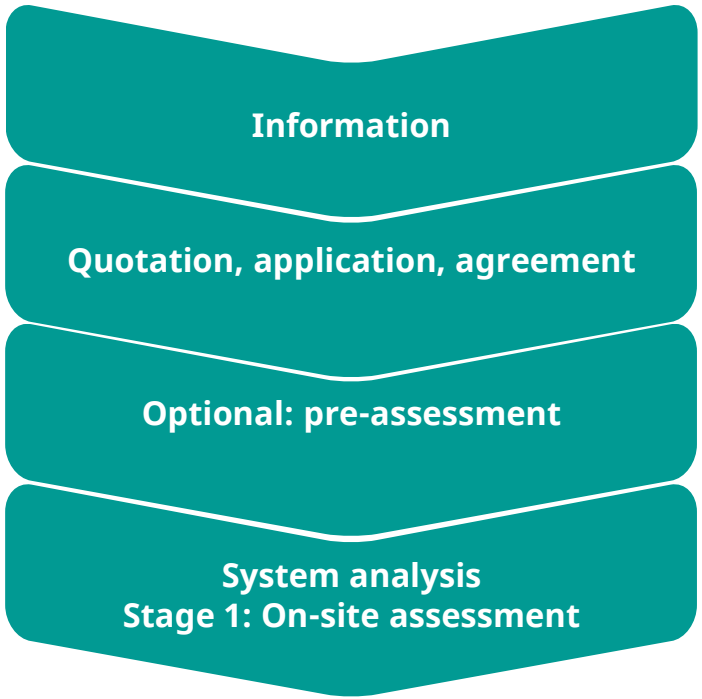
Note 2,0 (grade)

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



Certification process

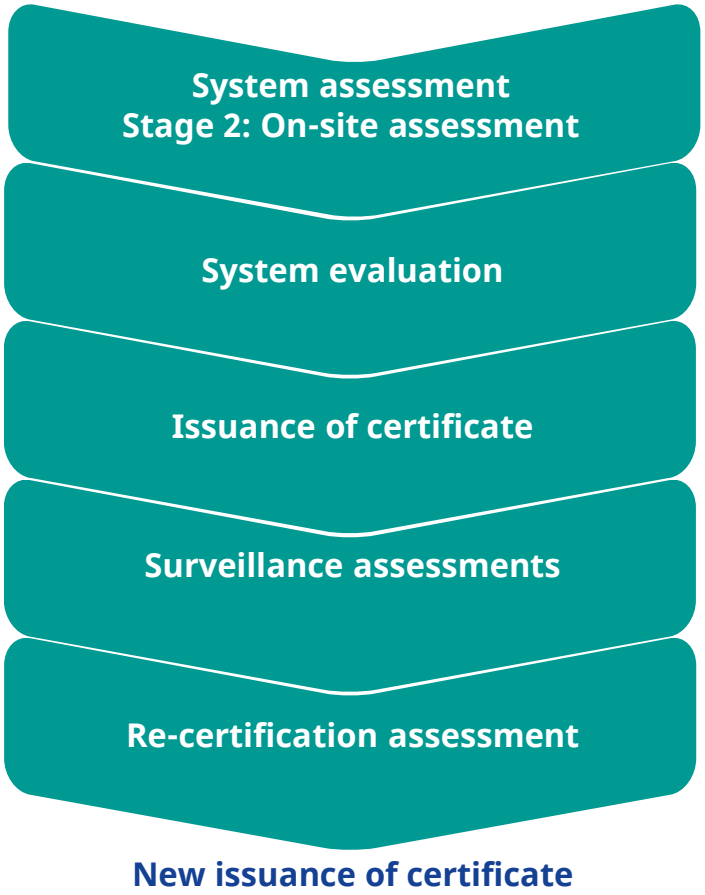
ISO13485/ ISO9001/ ISO15378/ MDSAP / TCP III



- 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.

Certification process

ISO13485/ ISO9001/ ISO15378/ MDSAP / TCP III



- 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.

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

INFORMATIONEN

Public Information

For information regarding our services, please visit www.dqsglobal.com or contact us at any of our events. Naturally, you can also contact your customer service representative or our sales staff via email: sales-med@dqs.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 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 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 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 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.
- Recognized as EU Notified Body Partner for TCP lll by Taiwan FDA
- 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

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