



# IMPACT

PRESENTED BY DQS INC.

Quarter 2, 2020

## Adjusting to the New Normal

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“Remote auditing has proven to be effective for most operations.”

Quarter 2 was brought in with the escalation of the COVID-19 outbreak, where we realized we needed to be flexible and address the changing needs of our customers with proactive solutions while following the recommendations of National Health groups and our Government. In this regard, and for the health and safety of both your employees and our auditors, we decided it best not to conduct on-site audits for most of this quarter. This action is warranted for the mutual protection of our organizations until the outbreak is under control.

DQS quickly adapted with remote auditing where allowed. The portion of the audit to be conducted remotely depends on the processes that can be effectively audited remotely, certification program allowances, technology and personnel available in your organization to support remote auditing. DQS firmly believes that remote auditing is as effective and efficient as on-site auditing.

The feedback from both customers and auditors has been positive overall with most wanting to continue with remote auditing for all or a portion of their audits in the future. For office functions, all have rated the remote audit as equally effective or more effective than an onsite audit. For production processes, most of the feedback has been positive. Where improvement was cited, it has been primarily due to needing an improved setup related to using a cellphone or tablet for an extended period

In order to continue to protect the health and safety of your staff and our auditors, our preference is to conduct remote audits to the maximum extent possible throughout the rest of 2020. Many of you will have visitor restriction policies that may affect our ability to

get on-site even during the reopening phases. Based on our customer feedback and auditor experience, remote auditing has proven to be effective for most operations.

We thank our many customers who have embraced this alternative approach. For those that are hesitant still about accepting remote auditing, DQS has provided support resources including videos showing the use of ICT in some mock audit scenarios: <https://dqsus.com/remote-auditing/>

None of us know how long this virus is going to impact our business operations and employees. Fortunately, we can maintain your certificate safely even during these uncertain times. While the physical DQS offices in Schaumburg, IL and Islandia, NY closed in March, all staff are working from home and continue to be ready to assist you. In Quarter 3, staff are starting to return to the office in Schaumburg a few days a week. Our entire organization is here to assist you if have any questions on the above. We pass on our wishes for the continued success of your organization and the health and safety of your management and staff during this pandemic.



## ADDITIONAL OFFERINGS

### Pandemic Due Diligence Assessment

The COVID-19 pandemic has us all questioning if we had done enough for a disaster like this. Do you know how your preparedness plan measures up? This assessment is an online tool for businesses to get independent confirmation

### ISO 22301 iAssessment

The ISO 22301 Business Continuity Management certification has helped companies ready for the disruption we are currently experiencing. Now DQS CFS has created an iAssessment to evaluate conformity remotely.

This MDD/MDR letter was drafted by sgd Dr. Thomas Feldmann and sgd Michael Bothe, the Head and Co-Head of Notified Body

## New MDD/MDR Timelines Letter Set in Q2

We are currently living in extraordinary times. Established certainties are being shaken with breath-taking speed. Something that was irrevocable yesterday, no longer holds true today. Only a few months ago, very few of us would have thought that a virus could have such devastating global consequences.

The EU Commission's initiative to postpone the date of effectiveness of the EU Medical Devices Regulation (MDR) by one year, should also be seen from this perspective.

This gives the member states, health care institutions and manufacturers of medical devices the opportunity to give priority to the fight against the pandemic.

For this reason, the moratorium on the general postponement of the transition period by one year, was decided by an overwhelming majority of the European Council on April 17, 2020. Although the member states still have to give their formal consent, they will take into account the unprecedented challenges of the coronavirus pandemic, and, the need to increase the availability of essential medical devices while continuing to guarantee the health and safety of patients when making their decision.

How does this scenario affect the activities of Notified Bodies?

After the effects of Corrigendum II, which we informed you about in December, you are now free to submit applications under the MDD again.

However, please understand that we can only confirm this with the legally binding publication in the official journal of the European Commission.

Now is also the ideal point in time to reconsider your current strategy for the changeover to MDR. So far, this has been determined by two cornerstones: the end of the transition period (5/25/2020) and the expected designation date of DQS MED, which is now imminent. Only the approval of the European expert committees and the member states is still missing - a mainly administrative process that should be completed by the end of June.

This results in two main options with the following deadlines

Option 1: Use of the new leeway MDD (05/25/2021)

a.) New submission of products under the MDD

- Application until 9/30/2020
- Provision of documentation by 10/31/2020

b.) Subsequent notification of significant changes to the product under the MDD

- Application until 10/31/2020
- Provision of documentation by 11/30/2020

c.) Recertification according to MDD

- Application until 11/30/2020
- Audits until 3/15/2021

Option 2: Transition to MDR

a.) Submission of applications

- After the designation of DQS MED, expected from 7/1/2020
- Provision of the technical documentation (all III, IIb implants / sample IIa, IIb, I); expected from 8/1/2020

b.) Submission of documents for stage 1 audit (on-site)

- expected from 9/1/2020

c.) Stage 1 audit expected to be carried out from 10/1/2020

d.) Stage 2 audit expected to be carried out from 11/1/2020

e.) First certificates expected still in 2020

Of course it is also possible to list products on both certificates in parallel.

Upon completion of your re-evaluation, we will ask you to fill out the Capacity Requirements Survey for your company, which can be found at <https://www.dqs-med.de/gut-zu-wissen/mdr-starter-kit-1>. This will give us the opportunity to pre-plan procedures and actively contribute to the highest possible degree of planning security.

Please send the completed and signed form to MDR@DQS-Med.de by 5/15/2020.

This link also provides you with the first of two starter kits. This contains information on the course of the conformity assessment procedure, a short guideline for technical documentation and useful links to the working papers of the respective stakeholders. In this way, we hope that we have been able to support you in your preparations.

## MORE ADDITIONAL OFFERINGS

### Hello Hygiene

The hotel business has been highly affected by the COVID-19 pandemic. Hello Hygiene is a standard for hotels to have independent confirmation that they have taken necessary preventative measures for hygiene and safety.

For more information on these offerings, go to [dqsus.com/pandemic-standards](https://dqsus.com/pandemic-standards)

### iAssessments

Setting up a management system for conformance to ISO 9001, ISO 14001, or ISO 45001? Measure your readiness prior to the DQS audit remotely with iAssessments. Learn more at <https://remote-audits.com/services/i-assessment/>

## The New World of Remote Auditing

The industry was seemingly thrust into the world of remote auditing at the rapid spread of the COVID-19 earlier this year, but it was something DQS Inc. was training staff on already. Remote audits go over the same processes and procedures as onsite audits, but they utilize technology to conduct the interviews, document review, tours and more.

Remote auditing has multiple benefits, especially for those who have employees who would normally travel in to the headquarter office for the audit.

### Benefits of Remote Audits

- Reduce social contact, complies with visitor restrictions and state travel orders
- Accommodates maintaining certification even when work from home guidelines are in place in your organization.
- Environmentally friendly – significant reduction in carbon footprint
- No auditor or customer travel costs
- Easy to use and proven technologies to facilitate with the same experienced auditors
- Attend the meeting from anywhere, when you have to
- More flexibility in planning for your team, without the need to attend in person
- In some cases, the audit can be fully remote while others are split between remote and on-site.



### Partial Remote Audits

If you are not sure on having a fully remote audit or DQS determines that some higher risk processes must be audited onsite, we can perform a partial remote. Partial

remote audits can be conducted two ways by either having part of the audit team onsite and part remote or by conducting the audit in two phases. Here are a few examples:

One auditor is onsite while the other is auditing remotely. The remote auditor will cover more of the leadership and support related processes while the onsite auditor covers topics that require more of a visual of the operation such as production, laboratory or warehousing processes. Where possible, the onsite audit is one that is more local to the facility. This still gives you the benefit of reduced travel costs as well as the comfort of having an auditor on site.

One auditor is assigned for the full audit and remotely conducts the portion that can effectively be audited remotely. The second part of the audit can then be conducted onsite. This option also works nicely if the facility has only partially reopened or if some of the management and support staff are working remotely still. This still results in lower travel and living costs based on a reduction in hotel and meal expenses for the audit days that are conducted remotely.

### Blended Onsite yet Remote Approach

In the current environment of social distancing, we also recognize that some members of our client's team are operating remotely every day. Where logistically practical, DQS auditors can come onsite and conduct aspects of the audit in the traditional manner and then use remote auditing techniques from a conference room for processes that are currently being conducted in the virtual "work from home" space. Or in some cases, we use a mix of techniques for production areas due to communication constraints of PPE. They may observe production activities and review physical aspects like machine settings and product traceability and status marks in the physical environment. Then they can conduct some interview portions of the audit using technology from the conference room.