Consequences of the Medical Devices Regulation (MDR) for Notified Bodies and Manufacturers

"I expect that there will be manufacturers who will totally underestimate the situation."

Interview with Klaus-Dieter Ziel, MEDCERT

The coming into force of the EU Medical Devices Regulation (MDR) raises many fundamental and detailed questions that the Medizinprodukte Journal is continually attempting to deal with via themed papers and contributions. In addition, we carry out interviews with experts in the real world, knowing very well that many answers are probably only snapshots and are above all their own personal opinions. In this manner, the Medizinprodukte Journal hopes to give readers – via this close contact with everyday practice – thorough expert contributions and this enable them to improve the quality of their everyday practices.

In this issue, Klaus-Dieter Ziel expresses his views. He is the manager of MEDCERT, one of the larger Notified Bodies in Germany.

Mr. Ziel, the MDR is now in force. A three-year transition period sounds like a lot. How does a notified body prepare for this?

Our aim is to submit our documents for designation in accordance with the MDR as early as possible, which means by 26 November 2017, to the German regional central body for health protection for drugs and medicinal products (ZLG[1]). This is our absolute priority, and all other activities are subordinate to this aim. The ZLG has then a maximum of 30 days to check our documents and if everything is in order, to pass them on to the committee. The submitted documents must be of high quality. We cannot afford subsequent amendments that take up extra time because we would certainly miss the top "launch pads" that are allocated by the committee for the subsequent joint assessments.

We are aware that we must be among the first designations; we want to switch clients from the MDD (Medical Device Directive) to the MDR (Medical Device Regulation) before the end of the transition period; but all the other bodies want to do that, too.

[1] https://www.zlg.de

What is Germany's competitive position compared with other countries?

The ZLG knows very well that we in Germany, because of the large number of notified bodies and the resulting time requirements, are at a disadvantage for the assessment of the application documents, when compared with countries that have only one or two notified bodies. It is trying to counter this disadvantage by promptly providing assessment capacities. There is currently a draft document indicating the documents that we have to submit to the ZLG. This includes, among other things, our QM documentation that describes in detail our procedures for compliance assessments in accordance with the MDR.

We began in August 2016 to become thoroughly acquainted with the MDR based on the MDR draft of June 2016. When the final version was published on 25 May 2017, we started the gap analysis to identify the requirements of the MDR relevant to us and at the same time to assess the effects of it on our QM documentation. At the moment, around 10 people from different divisions are working on the work packages assigned to them. This is a huge task that involves considerable capacities until the documents are submitted to the ZLG.

We are building up our MDR QM documentation at the same time as and in addition to existing MDD QM documentation. The advantage of this is that we can separate these two systems from each other completely, and after 2024, when the last MDD certificates become invalid, we will be able to simply annul the MDD QM documentation.

What are the core tasks that are being worked on as a priority as a notified body, and what can be done at the end of the transition period?

As already mentioned, the revision of our QM documentation is our uppermost priority so that we can adapt to MDR requirements. For the joint assessment, hopefully in the summer of 2018, but if possible earlier, we still have to work on the model compliance assessment procedure for the various risk classes and product types.

After the joint assessment, we have to deal with any pending matters and before designation worldwide in accordance with MDR, and all employees will have to be trained on the new procedures and our new QM documentation. Based on our current level of knowledge, we reckon, in the best-case scenario, on designation during the first half of 2019, or possibly not until the middle of 2019. This means we have around another 12 months to start switching current MDD clients to MDR.

At the moment, it looks unlikely that we will manage to complete the switch by 26 May 2020, the end of the transition period, for all MDD clients, even if all clients are prepared properly and on time for the MDR. At the same time, we are trying hard to find, take on and train the addition employees – which with a little luck, we'll manage to do – and whom we'll need for the new challenges. We already known that each switch to the MDR is to be treated at the very least like an initial certification that requires more, and in some cases, considerably

more time than, for example, a re-certification or annual monitoring in accordance with MDD.

We can only recommend that all clients prepare for the switch from DIN EN ISO 13485:2012 to DIN EN ISO 13485:2016 as quickly as possible and complete it at the latest by 2018 so they can concentrate specifically on the switch to MDR. A switch to MDR along with DIN EN ISO 13485:2016 is in theory possible, but we think that it's better to complete it in two stages.

Many manufacturers are now considering whether they want to avail themselves of the modified transition period and the continued validity to continue to use certificates in accordance with the Directive to put medical devices on the market after 27 May 2020. To do this, it would be necessary to carry out re-certification within the next three years. Have notified bodies sufficient capacity for this and have they planned for it?

The wish to carry out re-certification in accordance with the MDD is, based on our current knowledge of the additional resources that would be required, not really possible. If it were indeed possible, then at the latest only until we have designation in accordance with MDR. After that, we will need all our capacities, in the first instance, to switch our MDD clients to MDR and not for re-certification in accordance with MDD. Building up capacities for early re-certification in accordance with MDD and at the same time switching clients from MDD to MDR would mean that we would have to almost double the number of our main auditors by the end of 2018. That isn't possible, and the market would not be able to supply the required number of personnel at all. If manufacturers plan to use MDD certificates for additional years after the end of the transition period, then they should know that certificate changes will no longer be possible.

Our experience shows that many certificates change several times over a period of five years, for example to include or remove products, to make changes to the address, or to make changes to the legal entity etc. After the end of the transition period, it will no longer be possible because the notified body won't be allowed to issue any more modified, new MDD certificates. This means that the manufacturer requires *ad hoc* MDR certificates. All manufacturers that plan to use their MDD certificates after 26 May 2020 should know and realize this. I am sure that some manufacturers are going to get a few "surprises".

Is it feasible for notified bodies to operate simultaneously according as a designation according to the Directive and as a designation according to the Regulation?

We must distinguish between two situations for the notified body: first, simultaneous operation until 26 May 2020 and second, simultaneous operation between 26 May 2020 and 27 May 2024. Furthermore, simultaneous operation by the manufacturer is also possible where some products still hold an MDD certificate and other products already hold an MDR certificate. In principle, it is possible for both the notified body and for the manufacturer to maintain simultaneous operation.

After 26 May 2020, the end of the transition period, notified bodies must continue to monitor MDD still valid certificates annually. Monitoring will, however, not continue in the way the manufacturer has been used to until now; instead, the notified body will assume certain aspects of the MDR as part of its monitoring activities.

If a manufacturer has both MDR and MDD certificates, it must be aware that the notified body has to plan and implement two different annual monitoring audits.

Are you assuming simultaneous designation of bodies that have requested a new designation or will applications be in a race, on a first-in, first-out basis?

How the committee will allocate incoming applications regarding joint assessments has not yet been established, but it is certainly one of the most burning questions. The first five to ten notified bodies that are allocated their joint assessment still have, in my opinion, a good chance of starting to switch their clients to the MDR in 2019. For all other bodies after that, I think that the likelihood of that will be small.

The committee has already announced that it would like to designate several notified bodies from the first round of joint assessments at the same time, which, all in all, will cause delays and will mean a further reduction to the already short transition period.

In principle, a first-in, first-out procedure sounds feasible from the point of view of competition. We should, however, not forget that with such a procedure, notified bodies from countries with only a few or one body may have an advantage, and we, in Germany, will be at a disadvantage, because the time the notified authority needs to assess the documents provided by the applicant and to pass them on to the committee is of crucial importance for the “launch pads” to be allocated.

It is expected that at least 20 to 30 applications will arrive at the committee at the same time; according to what key should “launch pads” be allocated fairly? First-in, first-out? Or by country? Or by size? However the committee decides to allocate the incoming applications, in my opinion, there will be more losers than winners.

From when do you realistically think that the first notified bodies will be able to take on their tasks and accompany a manufacturer through the certification process according to the MDR?

I think that in the best-case scenario, notified bodies will be able to start switching to MDR at the start of 2019. At the same time, I hope that there will already be manufacturers that are well-prepared for their switch. Unfortunately, in practice, several things have become apparent: for example, at the end of the transition period for the MDD at the end of June 1998 or the higher classification of joint implants for September 2009 or 2010, manufacturers tended to complete their preparations too late rather than too early.

Do you have any advice that you could give to manufacturers that do not yet have a certificate in accordance with the Directive (class I products) and now, because of the higher classification, have to apply to certification in accordance with the Regulation from 26 May 2020?

All manufacturers can assume that notified bodies will give priority to existing clients for certification procedures over new clients. So, I recommend that manufacturers that are not yet the client of a notified body (e.g. because they only market class I medical devices) be certified in accordance with DIN EN ISO 13485.

Should these manufacturers quickly apply for a higher classification in accordance with the Directive or market products as "sterile" so they can also take advantage of the continued validity of Directive certificates?

I am not sure what you mean by "higher classification in accordance with the Directive". Without a change to the purpose of the product, there can be no change to the risk class.

Certification in accordance with DIN EN ISO 13485 is possible in any case. They should set deadlines as early as possible before the end of the transition period with the notified body, as soon as it looks like it will receive designation for MDR.

Is there any advice for manufacturers with existing certificates on how they can make best use the short transition period to manage the transition with the notified body without any conflicts regarding time and content?

I advise all manufacturers to get to grips as quickly as possible with the MDR. Based on presentations I have done on this matter, I have unfortunately realized that very few manufacturers appear to be aware of the urgency. They appear to be putting off the project because the end of the transition period is still two and a half years away.

I'm expecting there to be manufacturers that will totally underestimate the situation and then will try, in a panic, to update their QM system and their technical documentation to comply with MDR.

Manufacturers with existing certificates should have completed their MDR project by the latest by the end of 2018. In 2018, the notified bodies should know when their joint assessment is planned for. It will be possible to assess, based on this, from when the MDR designation will be available in the best-case scenario. Good, open communication from the notified body with the manufacturer and from the manufacturer with the notified body will contribute to providing information on the situation regarding the designation in accordance with MDR so they can incorporate this into their own schedule. The manufacturer should inform the notified body at least 6 months before the next audit of its intention to switch to MDR. Then, the notified body will have enough run-up time to take into account the desire to plan for the audit and the necessary additional work.

What effect do you think Brexit will have on the designation of British notified bodies and what does this mean for manufacturers?

Brexit was initiated at the end of March 2017 (triggering of article 50). This means that, after the contractually required negotiation phase of two years, we can expect the United Kingdom to leave the EU in March 2019, which to a large degree clashes with the application and designation process for the MDR.

I expect that British notified bodies will use their offices in other EU countries to submit their application, for example, in the Netherlands. If the body is then designated by the Dutch authority, its reference number will change. This in turn means that clients will have to change their reference, which in some cases, may be very time-consuming and expensive. I am nervous about how the market will react to that.

In the medium term, I expect that the committee in the United Kingdom will sign an agreement on the mutual recognition of compliance assessments, similar to what we are already familiar with for Australia or Switzerland. This will, however, certainly not take place before 26 May 2020.

What is, in your view, the most important change in the MDR compared with the MDD?

There are, in my opinion, many relevant differences in the MDR, compared with the MDD, so it is difficult for me to refer to one particular change.

What surprised us greatly was that there were *de facto* new risk classes were of particular relevance for the compliance assessment. In addition to risk class I – that already existed in MDD – including I sterile and I with measurement function, IIa, IIb and II, in the MDR there are new classes, namely class I, reusable, IIb, implantable, and active IIb medical devices that deliver or remove medicinal products. In particular, manufacturers in the last two product classes stated will have to complete a much more thorough and time-consuming check because the scope of the assessment of technical documentation, e.g. in the case of class IIb, implantable medical devices, will be considerably higher, and active IIb medical devices that deliver or remove medicinal products have to undergo a time-consuming peer review procedure, the so-called scrutiny process. In the past, manufacturers usually carried out a procedure in accordance with annex II of the MDD which compared with the MDR was much less onerous. I think that many manufacturers will be affected by this.

The MDR allows for additional details and requirements being specified in the future through additional Implementing Acts. What does this mean in your view for you as a notified body and for the manufacturer?

Yes, the MDR allows for 34 so-called Implementing Acts and 10 Delegated Acts. Based on current knowledge, we can assume that after the end of the transition phase, ie after 26

May 2020, work will be carried out on a lot of documents. These Implementing Acts will contain detailed descriptions and requirements that do not have to be given in this way for the MDR. Among them, there may be new things that may lead to changes to the procedure and requirements both for the notified bodies and for the manufacturer.

At the moment, we are not assuming that it will be quieter at the end of the transition period. We believe that for a few years, after 2020, we will continually have to incorporate new requirements into our procedures. This then, of course, applies similarly to manufacturers. I can promise you, it won't be boring.

And the following question to finish off: how do you personally think the next three years will go?

I'm expecting a hectic, occasionally chaotic time. We all know that a huge challenge awaits us and the manufacturers. In light of this, we cannot completely forget the rest of the regulatory environment. What do I mean by that? In addition to the massive changes from the MDD to the MDR – for example the switch to ISO 13485:2016 must be carried out, revision 4 of the Meddev 2.7/1 on clinical assessments must be completed, and CMD-CAS[2] procedures in accordance with Canadian legal provisions must be switched by the end of 2018 to the procedure in accordance with MDSAP[3], to cite what are, in my view, the most relevant changes. I compare these challenges facing manufacturers and notified bodies with the period between 1995 and 1998 when we all had to deal with the compliance assessment and CE marking of medical devices. Now, the regulatory changes before us are operating at quite a different level compared with around 20 years ago.

Many thanks for this interview.

That interview was held by MPJ –co-publisher Dr. Volker Lücker

Translation from German; the original version: Interview MPJ.

[2] Canadian Medical Device Conformity Assessment System
[3] Medical Device Single Audit Program